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Guidance for the Reregistration of Pesticide Products Containing Heptachlor as the Active Ingredient

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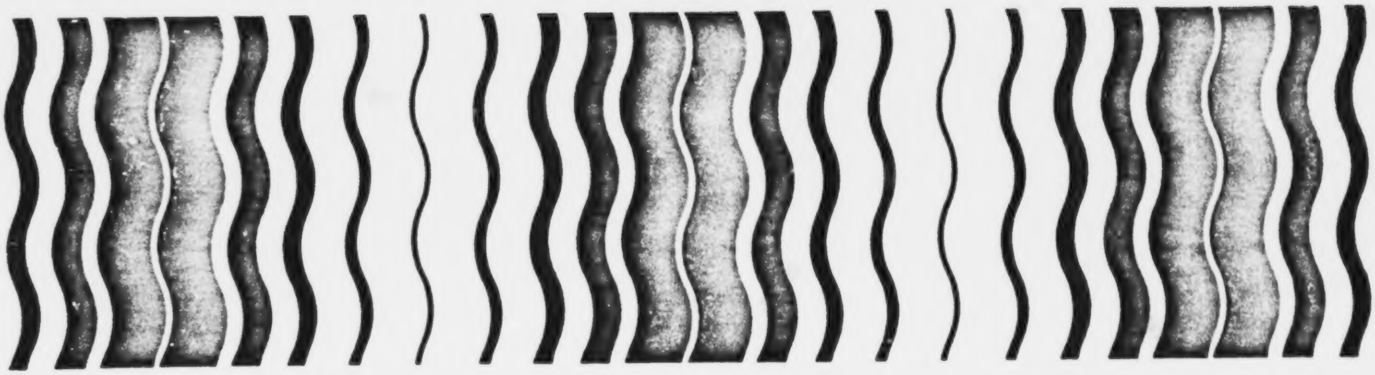

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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS
CONTAINING
AS THE ACTIVE INGREDIENT
HEPTACHLOR

EPA CHEMICAL CODE NO. 044801

Case No. 0175

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

December 31, 1986

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I. INTRODUCTION

The Registration Standards Program

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring the product and labeling into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and are reviewed on the basis of a ranking scheme giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses (See Section IV - Regulatory Position and Rationale). Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. You should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as your products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICAL

The following chemical is covered by this Registration Standard:

Common name: Heptachlor

Chemical name: 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-4,7-methano-1H indene

Other names: 1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-4,7-methanoindene; E-3314; Velsicol 104; Heptagran; Heptalube; heptachlore; Drinox H-34; Gold Crest H-60; Heptamul; and Heptox

CAS Registry number: 76-44-8

EPA Pesticide Chemical Code (Shaughnessy) number: 044801

Empirical Formula: $C_{10}H_5Cl_7$

Molecular weight: 373.3

Chemical/Physical Characteristics:
Color: white (pure); light tan (technical)
Physical state: crystalline solid
Odor: mild camphor-like odor
Melting point: 95-96°C
Boiling point: 135-145°C at 1-1.5 mmHg
Solubility: practically insoluble in water, but soluble in ethanol, xylene, carbon tetrachloride, acetone, and benzene
Density: 1.65-1.67 g/ml at 77°C (pure); 1.65-1.67 g/ml at 65°C (technical)
Vapor pressure: 0.0003 mmHg at 25°C (pure); 0.015 mmHg at 65°C (technical)
Stability: stable in daylight, air, moisture, and moderate heat

B. REGULATORY HISTORY

Heptachlor was first registered for use in the United States under the early FIFRA in 1952, and was produced commercially the following year. It was used extensively until the 1970's as a broad spectrum insecticide on a wide variety of agricultural crops, with the major use on corn. It also had other non-agricultural uses including seed treatment, home and garden uses, and termite control.

In 1974, the EPA Administrator proposed cancellation of nearly all registered uses of heptachlor and chlordane (a structurally related cyclodiene insecticide whose regulatory history closely parallels that of heptachlor's) for reasons that included the cancer risks posed by both compounds and their persistence and bioaccumulation throughout the food chain. Human monitoring data collected between 1970 and 1972 showed heptachlor epoxide (heptachlor's major degradation product) and oxychlordane (a metabolite of chlordane) present in the adipose tissue of a vast majority of the American people; heptachlor epoxide was found to be present in a substantial percentage of human milk samples and in stillborn human fetuses and neonates, indicating a placental transfer from mother to child (39 FR 41298).

All heptachlor uses subject to the Agency's cancellation and subsequent suspension notices, including all food uses, were ultimately cancelled. The few uses that were not cancelled in 1978, specifically field corn, seed treatment (for corn, wheat, oats barley, rye, and sorghum), citrus, pineapple and narcissus bulbs, were phased out gradually over a five year period of time ending on July 1, 1983. Limitations on production and distribution of technical heptachlor for each phased-out use were imposed (PR Notice 78-2).

Tolerances for heptachlor were not revoked at the time of cancellation for food and feed uses because of the compound's persistence in the environment and the expectation that residues would be present in raw agricultural commodities for a significant time period. However, EPA is now proceeding to revoke these tolerances, and replace them with action levels for unavoidable residues resulting from environmental contamination, in accordance with a September 1982 agreement among the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and EPA entitled "Policy Statement on the Revocation of Tolerances for Cancelled Pesticides" (47 FR 42956). On December 11, 1985 (50 FR 50643), EPA published a proposed rule under the Federal Food, Drug, and Cosmetic Act (FFDCA) to revoke all tolerances for residues of heptachlor in or on food and feed commodities. The final rule is scheduled for publication in the Federal Register in early 1987. There are also several existing action levels for heptachlor that were previously adopted by the FDA to cover unavoidable residues in food and feed commodities where no tolerances had been established. In conjunction with the revocation of tolerances for heptachlor, EPA is recommending that most of these existing action levels be lowered (see section III.E of this Registration Standard).

Certain uses of heptachlor were specifically exempted from EPA's suspension and cancellation actions because they were believed to result in insignificant exposure and, consequently, insignificant risk. Registrations were retained for subsurface termite control, fire ant control in buried cable closures, and dipping of roots or tops of non-food plants; a use which was subsequently cancelled voluntarily at the request of the registrant. Under the Administrator's clarification notice of July 14, 1975, above ground use of heptachlor using current control practices; which includes a registered wood impregnation method, was permitted (40 FR 30522).

As an interim regulatory measure early in its review of the termiticides, EPA initiated, in 1981, a Label Improvement Program (LIP) intended to reduce the potential risks of termiticide use primarily by reducing the possibility of misapplication that may result in contamination of treated structures and high exposures to occupants. For heptachlor and other termiticide products, required label changes included specific precautions concerning application near vulnerable areas such as domestic water supplies (cisterns, private wells, etc.), near heating ducts, and around structures with sub-floor crawl spaces, and warnings against routine (yearly) retreatment.

The termiticide use of heptachlor and other pesticides registered for termite control was subject to a preliminary review of risks and benefits conducted by EPA, with findings presented in a November 1983 report, "Analysis of the Risks and Benefits of Seven Chemicals Used for Subterranean Termite Control." This review of the termiticides was in part prompted by a General Accounting Office (GAO) report entitled "Need for a Formal Risk/Benefit Review of the Pesticide Chlordane," which specifically cited contamination problems discovered in U.S. Air Force military housing where chlordane, the most widely used termiticide chemical, had been applied for termite prevention and control. Rather than focusing solely on chlordane, EPA took the more comprehensive approach of reviewing available risk and benefit data on the various termiticide alternatives (i.e. aldrin, dieldrin, heptachlor, lindane, pentachlorophenol, and chlorpyrifos) as well as chlordane.

In summary, the Agency found that the benefits of the termiticides, particularly the chlorinated cyclodienes (chlordane, heptachlor, aldrin, and dieldrin), were generally very high, but definitive health and exposure data were lacking to support risk assessments for regulatory purposes.

Following the issuance of the 1983 report, "Analysis of the Risks and Benefits of Seven Chemicals Used for Subterranean Termite Control," EPA issued, early in 1984, a Special Data Call-In for termiticides requiring registrants to provide the following chemical-specific studies to support a more comprehensive risk assessment of each termiticide:

- A one-year indoor air monitoring study in homes of various construction types, treated for subterranean termite control in accordance with label instructions as revised by EPA's termiticide LIP;
- General metabolism studies, one in rats and one in mice, giving special consideration to pharmacokinetics;
- Five short-term mutagenicity (gene mutation) assays; and
- A subchronic inhalation study in rats to assess the potential toxic response from the inhalation route of exposure.

The status of these data requirements for heptachlor is as follows:

Preliminary results from the 90-day pilot phase of the heptachlor indoor air monitoring study have been submitted. EPA has requested that the registrant submit certain data including gas chromatography-mass spectroscopy (GC-MS) data in order to validate and correctly interpret the preliminary results. The metabolism data required from the registrant have also been submitted and reviewed. No further metabolism testing is required. The mutagenicity data requirements have not been fully satisfied, and additional mutagenicity studies are being required under this Standard. The registrant submitted a subchronic inhalation study which is considered invalid because the wrong technical was used (chlordane), and the lowest dose tested in the study was 20 times higher than the National Academy of Science (NAS) airborne guideline of 0.005 mg/m^3, the lowest dose level requested by the Data Call-In. A new inhalation study for heptachlor is required (see Section III.B).

Finally, it should be noted that EPA's Office of Water Regulations and Standards has recommended water quality criteria for ambient water concentrations of heptachlor. EPA issues such criteria under section 304(a) of the Clean Water Act, which requires the Agency to publish criteria for water quality reflecting current scientific knowledge on the kind and extent of all identifiable effects on health and welfare which may be expected from the presence of pollutants in any body of water, including ground water. These ambient water quality criteria are non-regulatory in that they do not in themselves represent enforceable regulatory standards. However, they may be adopted with or without modification, by individual States and may thus become enforceable State water quality standards. Typically, States may modify EPA's criteria to reflect local environmental conditions and human exposure patterns.

The ambient water quality criteria recommended for heptachlor and its supporting scientific assessment is described in a 1980 document, "Ambient Water Quality Criteria for Heptachlor. (EPA 440/5-80-052)," which is publicly available through the National Technical Information Service (NTIS), Springfield, Virginia 22161 (telephone: 703-487-4650). Specific criteria, expressed as maximum concentration levels per liter of water, are recommended (1) for protection of fresh-water and salt-water aquatic life from acute toxic effects of heptachlor, and (2) for protection of human health due to exposure to heptachlor through ingestion of contaminated water or contaminated aquatic organisms.

C. USE PROFILE

The basic producer of heptachlor in the United Sates is Velsicol Chemical Corporation. In 1980, heptachlor, with some usage as a single active ingredient, but typically formulated with chlordane, accounted for approximately 15 percent (less than 2 million pounds of active ingredient) of the overall use of termiticides in this country. In 1985, the usage declined to a range of 0.75 to 1.0 million pounds of active ingredient. No usage information is available for heptachlor's minor uses.

There are twenty-two federally registered end-use products containing heptachlor as the sole active ingredient[1]. With the exception of one granular product, these are all emulsifiable concentrate (EC) formulations. Six EC end-use products contain heptachlor in combination with chlordane. In addition, one end-use product contains heptachlor in combination with pentachlorophenol. This product is a restricted use pesticide. Velsicol Chemical Corporation produces four formulation intermediates (three of which are heptachlor/chlordane combinations) and four (72%) technical products. There is one "special local need" registration under FIFRA section 24(c) issued to the State of California (CA-810012). All intrastate products are cancelled.

Heptachlor is registered for control of subterranean termites either as a preconstruction treatment for preventing termite problems or as a post-construction, remedial treatment. The termiticide is typically applied along the inside and outside of foundations; around the bases of supporting piers, chimney bases, plumbing and conduits; under filled porches, entrances and terraces; under floor structures resting on soil or gravel fill; and exposed soil areas under structures. Effective treatment requires the establishment of a chemical barrier between the wood in the structure to be protected and the termite colonies in the soil. Current control practices include trenching, rodding, subslab injection, and low pressure spray application. The State of California's 24(c) "special local need" registration allows for limited use of a chlordane/heptachlor product in crawl spaces where conditions do not permit trenching or rodding; application cannot be made more than 18 inches, horizontally, from the foundation, piers or pipes, and certain structures cannot be treated (i.e. houses with gravity type heating systems).

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[1] The Agency considers all currently registered end-use products containing heptachlor in combination with solvents or diluents to be sole active ingredient formulations. The Agency does not consider the solvents or diluents in these formulations to be insecticidal, and therefore must be declared as inerts.

Heptachlor, formulated as a five percent granular product, is registered for control of fire ants in buried pod mounted electric power transformers and cable television and telephone pedestals. Treatment consists of applying the product directly into the buried cable closure. Heptachlor, formulated in combination with pentachlorophenol, is a restricted use pesticide for the above ground preservative treatment of poles and stubs, timber structures, cuts and holes in treated wood, and exposed timber and lumber surfaces in buildings to control fungi, carpenter ants, wood-destroying beetles and termites. Application to wood surfaces is made by caulking gun, trowel, or brush. The product is not intended for general treatment of finished buildings.

The majority of heptachlor end-use products are labeled for use only by commercial pest control operators. In most States the applicator must be certified under 40 CFR 171.4 as a commercial applicator of pesticides.

III. AGENCY FINDINGS

A. SUMMARY

The Agency has reviewed all data currently supporting the registration of heptachlor. Based on the available data, EPA has reached the following conclusions. The points summarized below are presented in further detail, in the context of EPA's science findings and additional data requirements, in Sections B through D.

1. Technical heptachlor (74%) is moderately acutely toxic through the oral route of exposure. Additional data are required to fully assess the acute oral, dermal, and inhalation toxicity of this pesticide, as well as the subacute inhalation toxicity.

2. The Agency has concluded that the available data do not indicate that heptachlor causes acute delayed neurotoxic effects.

3. Heptachlor and heptachlor epoxide exposure may pose a significant health risk of chronic liver effects to occupants of structures treated with heptachlor.

4. The termiticide use of heptachlor may also pose an oncogenic risk of regulatory concern. Heptachlor and heptachlor epoxide are oncogenic in laboratory mice; the available test data in rats are inconclusive for assessing the oncogenicity of heptachlor/heptachlor epoxide in the rat. Thus, a new two-year rat oncogenicity study will be required. Evidence of oncogenicity is based on findings of increased incidence of liver carcinomas in C3H, CD-1 and $B6C3F_1$ mice, in both males and females, and at both medium and high doses. EPA will consider the forthcoming results of the indoor air monitoring study now underway to determine whether human exposure from the termiticide use of heptachlor results in risks of cancer and chronic liver effects that warrant regulatory action. The final results of this monitoring study are scheduled for submission to the Agency in February, 1987.

5. The Agency was recently apprised of three reported cases of optic neuritis (an inflammation of the optic nerve) associated with termiticide treatment of homes. To determine whether this human health effect is significant and whether heptachlor may play a role, the registrant must have eye tissue from the required two-year

rat oncogenicity study analyzed by neuropathologists specializing in optic tissue pathology. Since this study utilizes animals exposed via the oral route (as opposed to inhalation which may not produce 100% absorption of the test material), if an effect is present, it should be easily discerned by this type of exposure.

6. Laboratory data show that technical heptachlor is very highly toxic to warm- and cold-water fish species, and to freshwater invertebrates. Heptachlor is highly toxic to birds, based on acceptable acute dietary studies. Avian acute oral toxicity data are required.

7. The pesticide chlordane, a related cyclodiene termiticide, has been found in fish at levels exceeding the U.S. Food and Drug Administration action level at various urban aquatic sites in Iowa, Missouri, and Nebraska. Preliminary evidence indicates the source of this contamination may be surface water run-off from the termiticidal use of chlordane. These preliminary findings on chlordane raise the question whether the termiticide use of heptachlor could be contaminating surface water. Chlordane has similar physical and chemical properties to heptachlor; technical chlordane typically consists of 10 percent heptachlor.

   Therefore, the Agency is requiring a special study to determine whether heptachlor's use as a termiticide may result in contamination of surface water. This study is intended to provide information on (1) whether the termiticide use of heptachlor results in residues of heptachlor and its epoxide in drinking water and in fish for human consumption, and (2) whether fish and freshwater invertebrates are at risk of being exposed to toxic levels of heptachlor/heptachlor epoxide as a result of the termiticide use of heptachlor.

8. The extent of potential exposure to aquatic endangered species cannot be assessed until the results of the required surface water monitoring study are received.

9. The Agency is restricting the use of heptachlor termiticide products to Certified Applicators as specifically defined in label provisions prescribed by EPA in this Registration Standard. The Agency considers the subterranean termiticide application to be complex and to require a great deal of specialized knowledge and training not typical of other pesticide applications. The Agency is also concerned with the potential oncogenicity of these products and potential exposure to occupants of treated buildings. Data available to EPA show occurrence of misuse and misapplication of heptachlor termiticide products (refer

to Section III.D). The Agency believes that restricting its use would minimize inadvertent misuse and/or misapplication.

10. The Agency is restricting the use of the heptachlor five percent granular product registered for control of fire ants in buried pod mounted electric power transformers and cable television and telephone pedestals due to concern over potential exposure to applicators. Applicator exposure data are lacking and constitute a data gap. Restricted-use classification is required as an interim risk reduction measure until applicator exposure data have been received and evaluated.

11. In rats, the available data from five existing carcinogenicity studies are not considered adequate or conclusive, and a well-designed study in rats is needed to determine the carcinogenic potential of heptachlor epoxide in this species.

12. Although negative for mutagenic activity in bacteria, further testing in mammalian systems must be submitted to complete requirements for mutagenicity, specifically; mammalian cell gene mutation assays and somatic cell cytogenetic assays. Additional testing for promotional (epigenetic) activity is also required.

As a result of this Registration Standard review, the Agency has determined that certain additional or revised label restrictions are necessary. These include:

- Restricted use classification
- Revision of Existing Use Instructions
- Pesticide disposal procedures
- Worker protective clothing statements
- Fish and wildlife toxicity warnings
- Statement on carcinogenic and adverse liver effects in laboratory animals.

The Agency has also identified missing data necessary to fully evaluate the human and environmental risks associated with the use of heptachlor as a termiticide. These data must be developed in order to maintain registrations of existing products or register any new products containing heptachlor. A summary of these data gaps is given in Table 1. Please note that this is only a summary and complete details can be obtained by referring to the tables in Appendix I.

EPA will continue to evaluate the termiticide use of heptachlor in terms of the regulatory concerns identified in this Registration Standard as additional information becomes available. The Agency will continue to evaluate the risk of chronic liver effects in humans from exposure to heptachlor and also its potential oncogenicity and determine whether additional regulatory action is warrented.

The Regulatory Position and Rationale section of this Registration Standard discusses the Agency's position on each of the regulatory issues concerning heptachlor, and the Required Labeling section contains the specific wording required for each of the labeling provisions.

TABLE 1. SUMMARY OF DATA GAPS

(Please refer to the tables in Appendix 1 for detailed information regarding these requirements)

Toxicology

Battery of acute toxicity studies
Subchronic Inhalation Study -- rats (one-year)
-- guinea pigs or rats (two-weeks)

Chronic Feeding -- non-rodents and rats (heptachlor epoxide); non-rodents (heptachlor)
Oncogenicity -- rats (heptachlor epoxide)
Mutagenicity studies
Teratogenicity -- rats and rabbits
Optic tissue pathology -- rats

Environmental Fate/Exposure

Hydrolysis study
Aerobic and anaerobic soil metabolism studies
Aerobic aquatic metabolism study
Leaching and adsorption/desorption study
Soil dissipation: field study
Photodegradation in water
Special monitoring study of heptachlor residues entering surface water from sanitary sewers, sumps, and drainage tiles from home foundations known to have been properly treated with heptachlor
Applicator exposure studies
Indoor air exposure studies

Fish and Wildlife

Avian acute oral toxicity

[Pending results of the surface water special monitoring study and other environmental fate data, additional fish and wildlife data requirements may be imposed. These include, but are not limited to monitoring of residues of heptachlor in aquatic sites and chronic fish and wildlife toxicity studies.]

Product Chemistry

All product chemistry studies

B. PRELIMINARY HEALTH RISK ASSESSMENT

Numerous data gaps exist for heptachlor and few definitive conclusions can be made pending receipt of additional data. The following assessment is based on the data available.

1. Acute Toxicity. Adequate data are not available to fully assess the acute toxicity of heptachlor. Additional studies are required on acute oral, dermal, and inhalation toxicity. Based on acute oral toxicity testing using a 74 percent technical grade of heptachlor, heptachlor was found to produce moderate toxicity. The oral LD_{50} value for male and female rats was reported to be 208 mg/kg and 158 mg/kg, respectively, placing a 74 percent technical heptachlor in Toxicity Category II for oral exposure. No data gap exists for acute oral toxicity testing of manufacturing-use products containing this percentage of technical grade heptachlor; a data gap exists for other manufacturing-use products.

   Reported signs of acute intoxication are similar to those for the other cyclodiene pesticides, and are primarily related to the central nervous system (CNS). Symptoms include hyperexcitability, convulsions, depression, and death. There have been numerous incidents of acute intoxications in humans from heptachlor exposure among chemical plant workers; however, recovery has been complete and relatively rapid following removal from the exposure area. Based on available data including direct human evidence from these incidents, and the dissimilarity of heptachlor to known neurotoxic agents (i.e., organophosphates), the Agency concludes that based on the available data, heptachlor does not appear to cause acute delayed neurotoxic effects. For this reason, a delayed neurotoxicity study is not required.

   The Agency also concludes that heptachlor does not appear to be a skin sensitizer, again based on human exposure data. The data supporting this conclusion concern chemical plant workers who experienced the kind of repeated skin contact which is simulated in dermal sensitization studies under laboratory conditions without experiencing dermal sensitization.

   However, product-specific data are required so that EPA may assess the potential of heptachlor products to cause primary eye and dermal irritation. The purpose of the requisite primary dermal irritation testing is to determine the irritative or corrosive effects of a single dermal exposure at a dose level that is considerably higher than the dosage used in skin sensitization testing. The results of these primary eye and dermal irritation studies will be considered together with the results of required acute toxicity testing in determining the appropriate toxicity category for heptachlor products. Acceptable data on file place a 72% technical heptachlor product in Toxicity Category IV (mildly irritating) for primary dermal irritation; data gaps exists for other formulations.

2. Subchronic Toxicity. As noted previously in Section II.B, a subchronic inhalation study in rats was among the studies originally required by EPA through the Special Data Call-In issued for heptachlor in February 1984. The registrant submitted a study which centered on the use of chlordane with only about 10 percent of the test material being heptachlor. Thus, it is not possible to discern whether the toxicity noted in the study results from exposure to chlordane or heptachlor. The study is considered invalid for this reason and also because the lowest dose tested was not the National Academy of Science (NAS) guideline, as requested in the Data Call-In (DCI). The Agency has determined that a new rat inhalation study must be performed for a period of one year, rather than 90-days, as this exposure period more likely reflects typical human exposure resulting from termiticide use. The lowest dose level must be the NAS guideline level.

In available subchronic feeding studies with rats and mice, the primary subchronic effects exerted by heptachlor and its epoxide metabolite were reported to be liver effects; endoplasmic reticulum hypertrophy, enlarged central hepatic lobule cells, increased liver weight and liver lesions. Also noted were increased adrenal and thyroid gland weights. The subchronic studies on file with the Agency are considered inadequate to satisfy EPA's guideline requirements. However, the Agency is not requiring subchronic feeding studies for heptachlor, since the results from the chronic feeding studies can be used to assess effects releated to subchronic exposure.

Pending the results of the required acute dermal toxicity study, the requirement for a 21-day dermal study is reserved.

The registrant also must conduct additional inhalation studies of two week duration with either guinea pigs or rats to further delineate the irritative capabilities to mucous membranes of heptachlor, formulation solvents, and the combination (i.e. formulated products.).

3. Chronic Toxicity: Liver Effects and Oncogenicity; Setting a PADI

Liver Effects and PADI. Administration of heptachlor in chronic and subchronic feeding studies in mice and rats resulted in cellular degeneration and histopathological changes in the liver known as chlorinated hydrocarbon insecticide rodent liver (CHIRL). Liver toxicity occurred at doses as low as 0.5 parts per million (ppm), equivalent to 0.0125 milligrams per kilogram body weight per day (mg/kg/day), the lowest dose tested in a 60-week dog feeding study with heptachlor epoxide. Based on this lowest effect level (LEL) of 0.0125 mg/kg/day, EPA has calculated a provisional acceptable daily intake (PADI) level for heptachlor, for effects other than oncogenicity, of 1.3×10^{-5} mg/kg/day, by applying a 1,000-fold uncertainty factor. The PADI for heptachlor is based on the chronic feeding study of heptachlor epoxide, since this is the major storage metabolite of heptachlor [a NOEL for heptachlor alone is 3.0 ppm].

The PADI is considered provisional because the existing data base for heptachlor/heptachlor epoxide is lacking the following toxicology data: chronic toxicity in rats and dogs, rat oncogenicity, rat and rabbit teratology, and mutagenicity studies.

Oncogenicity. During the heptachlor/chlordane suspension and cancellation proceedings conducted between 1974 and 1978, the existing data concerning the oncogenicity of both compounds were subject to intensive evaluation. An updated assessment of the carcinogenic risks of heptachlor and chlordane has been conducted by EPA's Carcinogen Assessment Group (CAG) in accordance with the Agency's 1984 Proposed Guidelines for Carcinogen Risk Assessment (49 FR 42694; November 23, 1984). Based on this assessment heptachlor and heptachlor epoxide have been classified as Group B_2 (i.e, probable human) carcinogens, with cancer potency estimates (Q^{-1*}) of 4.5 and 9.1 per mg/kg/day, respectively.

The Agency's 1984 Proposed Guidelines describe the general framework to be used in developing an analysis of carcinogenic risk with regard to assessing the weight of evidence of carcinogenicity from human and animal studies. Based on the weight-of-evidence analysis of available data, chemicals are categorized with regard to their potential human carcinogenicity. Under EPA's classification system, Group A, "Human Carcinogen," is reserved for those chemicals for which there is sufficient evidence of carcinogenicity from human epidemiological studies. Group B, "Probable Human Carcinogen," is divided into subgroups 1 and 2. Group B_1 requires some human epidemiological evidence. Since existing epidemiological studies of heptachlor provide inadequate evidence of carcinogenicity due to methodological and data limitations, EPA does not have reason to classify heptachlor as a Group A or B_1. Under the carcinogen risk assessment guidelines, chemicals are categorized as Group B_2 carcinogens if there is "sufficient evidence" of the chemical's carcinogenicity from animal studies. Sufficient evidence of carcinogenicity is indicated by an increased incidence of tumors: (a) in multiple species or strains; or (b) in multiple experiments (e.g., with different routes of administration or using different dose levels); or (c) to an unusual degree in a single experiment with regard to high incidence, unusual site or type of tumor, or early age at onset. Group C ("Possible Human Carcinogen") chemicals are classified on "limited evidence" from animal studies. There is also a Group D ("Not Classified") and a Group E that is reserved for chemicals shown to be non-carcinogenic in animal and/or human studies.

In classifying heptachlor/heptachlor epoxide as Group B_2 carcinogens, the Agency considered all currently available data in both mice and rats. In mice, three long-term carcinogenicity bioassays of heptachlor and its epoxide independently conducted by investigators affiliated with the National Cancer Institute (NCI 1977b), the Food and Drug Administration (Davis, 1965), and the International Research and Development Corporation (IRDC, 1973b) are considered adequate for risk assessment by current scientific standards. In these studies, heptachlor was found to produce significant liver tumor responses in three different strains of mice (C_3H, CF_1, and $B6C3F_1$) in both males and females at both medium and high doses, with a dose-related increase in the proportion of tumors that were malignant. In rats, the available data from five existing carcinogenicity bioassays are not considered adequate or conclusive, and a well-designed study in rats is needed to determine the carcinogenic potential of heptachlor epoxide in this species. However, the available evidence in mice is considered sufficient laboratory evidence to warrant the classification of helptachlor as a Group B_2, probable human carcinogen.

Further support for this classification comes from the available evidence on the carcinogenicity of chlordane, and the induction of tumors by other chemicals such as aldrin and dieldrin, which are structurally related to heptachlor[2/].

Risk Assessment for Liver Effects and Oncogenicity. The Agency has received and evaluated preliminary results covering the first 90 days of a one-year indoor air monitoring study. The study reflected treatment of slab and crawl space (but not basement) houses with the pesticide product Termide, a formulation consisting of a 2:1 mixture of technical chlordane to technical heptachlor. In the samples collected, quantitative determinations were made for ambient air levels of 4 chlordane isomers, trans-nonachlor and heptachlor. The registrant reported that airborne residue consisted principally of heptachlor, with the chlordane isomers accounting for only a minor proportion. This finding conflicts with data available in the literature, which demonstrate chlordane as the primary residue. Because of this discrepancy, the Agency in conjunction with its Beltsville, Maryland laboratory, is working with the registrant of the study to interpret and validate the air monitoring data. In order to validate the air monitoring results, the registrant must verify by gas chromatography-mass spectroscopy (GC-MS) whether chromatographic peaks have been correctly identified as one of the four chlordane isomers, trans-nonachlor or heptachlor; determine whether all major epoxide breakdown products, especially oxychlordane and heptachlor epoxide, are present in ambient air; and identify the significant peaks (reflecting greater than 5% detector response above baseline) not presently quantitated.

Nevertheless, EPA is concerned about the potential human health risks of heptachlor based on limited literature values for ambient air levels of heptachlor/chlordane in treated homes, coupled with heptachlor epoxide's extremely low PADI (1.3 x 10^{-5} mg/kg/day), and high cancer potency value (Q^{*-1}= 9.1 per mg/kg/day). EPA will be considering the results of the indoor air monitoring study, once the validation data are received, together with the evidence on the oncogenicity of heptachlor to determine whether human

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2/ Chlordane, aldrin and dieldrin have also been classified as Group B_2 (probable human) carcinogens, based on significant tumor responses in multiple strains of mice; and in the case of chlordane, mice and rats.

exposure to heptachlor may be posing a human health risk of regulatory concern.

4. Mutagenicity Studies. The Agency has reviewed eighteen published articles, consisting of a total of 32 assays with technical heptachlor/heptachlor epoxide, some of which were submitted in response to the February, 1986 Data Call-In Notice. Of these assays, only 10 were found to be acceptable. Based on its review, the Agency has reached the following preliminary conclusions:

a. Heptachlor/heptachlor epoxide does not appear to be mutagenic in microbial or mammalian cells.

b. Although negative for chromosome damage in germinal assays, the potential for somatic cytogenetic activity has not been adequately evaluated.

c. The combined results of DNA repair assays indicate that heptachlor is not genotoxic in bacterial, yeast, or mammalian cells.

d. There is evidence suggesting that heptachlor, along with the other organochlorines, acts as a promoter, rather than initiator of cancer, although additional testing in mammalian cell systems is necessary to affirm the apparent absence of potential for direct genotoxic activity.

To complete regulatory requirements, the Agency is requiring additional testing, specifically; mammalian cell gene mutation assay with established test systems, e.g. mouse lymphoma (L5178Y/TK), or Chinese hamster (CHO/V79/HGPRT) cells *inter alia* and somatic cell cytogenetic assays, either *in vitro* or *in vivo*. Further, to confirm the potential activity of these chemicals in indirect (epigenetic) processes, the Agency is requiring the following: repair in mammalian cell systems, e.g., primary mouse hepatocytes or established cell lines: adequately controlled promotion assays, e.g., in cell lines already initiated (by viral transformation), or exposed to known active chemical initiators; mammalian cell transformation in systems with an established data base, e.g., C3H 10 T1/2, BALB 3T3, *inter alia*; assays for mitotic spindle effects (*in vitro* or *in vivo*), and/or involving other cellular mechanisms (e.g., oncogene activation), *inter alia*; and assays which can distinguish effects on replicative S-phase (scheduled) DNA synthesis from UDS, e.g., in primary hepatocytes from several species (mouse vs. rat/hamster).

5. Metabolism Studies.

Heptachlor is metabolized to heptachlor epoxide in biological systems. In studies with rats, it has been reported that heptachlor epoxide can be further metabolized to di- and trihydroxylated derivatives of dihydrochlordene and excreted. Heptachlor is also postulated to be converted to either 1-hydroxychlordene or 1-chloro-dihydrochlordene *via* another metabolic pathway and further metabolized to proposed excretion products by conjugation with glucuronic acid. There is not sufficient evidence that the production of the 1-chloro-dihydrochlordene species is a major degradative pathway of heptachlor. Since only the epoxide of heptachlor has been reported as the major storage metabolite, further determination of minor quantities of other possible metabolites is not warranted. There are no further metabolism testing requirements.

6. Teratology and Reproduction. A data gap exists in the area of teratology toxicity testing.

Several reproduction studies have been reviewed by the Agency and were adequate to set a NOEL of 1.0 ppm for reproductive effects to the young, the liver being the target organ of effect. No further testing is required.

In one study comprised of a limited number of male and female rats exposed for 7 weeks to heptachlor at dosages ranging from 1.5 to 10 ppm, exposure of dams or sires to doses ranging from 7 and 10 ppm resulted in increased pup death. Reproductive effects were absent in rodents being tested with heptachlor at 5 ppm and below; the lowest dose producing adverse reproductive effects (pup death) appeared to be 7 ppm in rats. A NOEL of 5 ppm was established.

In another study using a limited number of treated dogs (4 per sex) heptachlor epoxide was fed in the diet at 1, 3, 5, 7, and 10 ppm. Pups born to dams exposed to 7 and 10 ppm died, and pups born to dams exposed to 3 ppm exhibited liver effects. An LEL of 3 ppm was established with a NOEL of 1 ppm based on liver effects.

7. Applicator Risks. Because data on heptachlor, including surrogate data, are not available to characterize applicator exposure, the Agency is unable to assess the risks posed

to pesticide applicators as a result of dermal and respiratory exposures to heptachlor during application. In order to evaluate the risks of occupational exposure to heptachlor, the Agency is requiring the submission of appropriate dermal and respiratory data from applicator exposure monitoring studies.

C. ENVIRONMENTAL PROFILE

1. *Ecological Effects*. With the exception of avian acute oral toxicity testing, there are no ecological effects data requirements at this time. Existing data are adequate to show that heptachlor is potentially very highly toxic to both warm-water and cold-water fish species. The results of an acute warm-water fish study show an LC_{50} value of 13 ug/L for bluegill. In cold-water fish, the value was 7.4 ug/L for rainbow trout. Heptachlor is also very highly toxic to freshwater invertebrates on an acute basis. The 48-hour EC_{50}* for *Daphnia pulex*, *Pteronarcys*, and *Orconectes* are reported to be 42 ug/L, 1.1 ug/L and 0.5 ug/L, respectively. Acute dietary studies provide sufficient information to characterize heptachlor as potentially highly toxic to birds. Bobwhite quail, pheasant, and mallard ducks had dietary LC_{50} values of 92 ppm, 24 ppm and 480 ppm, respectively. The requirement for the avian acute oral LD_{50} test has not been satisfied.

Heptachlor epoxide has been reported to cause adverse effects in birds. In one study, it was reported to be responsible for adult mortality and reduced hatchling success in Canada geese nesting in the Columbia Basin, Oregon; the geese were believed to have fed on heptachlor-treated seed. Productivity of the American kestrel was also reported to be adversely affected by heptachlor. Since American kestrels are not seed-eaters, the presence of heptachlor epoxide in kestrel eggs was linked to contamination of the food chain. Reduced use of heptachlor in 1979 in the study area resulted in an immediate lowering of heptachlor epoxide concentrations in kestrel eggs the following year.

Besides its inherent toxicity, heptachlor epoxide is highly lipophilic and bioaccumulates in adipose tissue. This propensity to bioaccumulate could cause heptachlor to produce secondary chronic effects in exposed organisms. If the results of environmental fate data and/or monitoring data being required to determine whether the termiticidal use of heptachlor may be contaminating surface waters should raise concerns about potential heptachlor exposure to fish or fresh-water invertebrates, special monitoring of aquatic sites and chronic fish and wildlife studies may be required.

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* Environmental Concentration

2. Endangered Species. EPA does not have reason to believe that the termiticide use of heptachlor threatens any endangered species at this time. Concerns may be raised depending upon the results of the surface water monitoring study (see below).

3. Environmental Fate. The Agency is unable to fully assess the environmental fate of heptachlor, because acceptable data are lacking. However, available supplementary data do indicate general trends of heptachlor behavior in the environment. Heptachlor was immobile in both Hagerstown silty clay loam and Lakeland sandy loam soils based on upward movement in subirrigated soil columns. Heptachlor incorporated 7.5 cm at 5.6 kg ai/ha into a Rayne silt loam soil dissipated from the surface 0-23 cm with a half-life of 336-551 days. In field studies using heptachlor epoxide, an estimated half-life of 5-6 months was determined for Carrington loam soil. Additionally, in long-term studies in Beltsville, Maryland estimated half-lives ranged from 2 to 4 years. In long term experiments in Hawaii, applications resulting in concentrations of 89-503 ppm declined to 0.68-8.28 ppm heptachlor/heptachlor epoxide after 7 years. Nearby plots not treated with heptachlor had residues of 0.33-0.52 ppm after 7 years, indicating some mobility. Heptachlor is not expected to leach, since it is insoluble in water and should adsorb to the soil surface. However, additional data are necessary to fully assess the potential for ground-water contamination as a result of the termiticide use of heptachlor.

To assess the environmental fate of heptachlor in conjunction with its domestic outdoor use pattern, the Agency is requiring the following studies: hydrolysis; aerobic and anaerobic soil metabolism; aerobic aquatic metabolism; leaching or adsorption/desorption; terrestrial field dissipation; and photodegradation in water. In addition, a number of data requirements are reserved. Aquatic sediment dissipation data may be required, pending the results of the aerobic aquatic metabolism study. A fish accumulation study is reserved pending the results of the product chemistry requirement for an octanol/water partition coefficient study. Finally, depending on the results of the indoor air monitoring study now in progress, further testing may be required in this area. In addition, a special monitoring study is being required to determine the extent of surface water contamination from the termiticide use of heptachlor. The purpose of this study is twofold: (1) to determine whether and to what extent termiticide applications are resulting in residues of heptachlor and its degradate heptachlor epoxide in drinking water and in fish for human consumption, and (2) whether fresh-water fish and invertebrates are at risk of being exposed to toxic levels as a result of heptachlor's termiticide use.

This requirement arises from recent findings of the termiticide chlordane in fish at levels exceeding the U.S. Food and Drug Administration action level at various urban aquatic sites in Iowa, Missouri, and Nebraska coupled with preliminary data indicating that the source of contamination may be surface water run-off associated with the termiticidal use of chlordane. In 1985, the Iowa Department of Water, Air, and Waste Management sampled urban sources of chlordane, representing a range of potential urban sources. While sampling of storm sewers yielded negative results, trace amounts of chlordane were found at a water treatment plant (0.18 ppb), a sanitary sewer showed measurable amounts (2.5 and 4.7 ppb), and a significant amount of chlordane was found in a sump pump (180 ppb). These preliminary findings on chlordane raise the question whether the termiticide use of heptachlor could be contaminating surface water. Chlordane and heptachlor, both of which are chlorinated cyclodiene pesticides, have similar physical and chemical properties as well as similar application patterns, and it is reasonable to expect that they may exhibit comparable behavior in the environment.

D. ADDITIONAL CONSIDERATIONS: HEPTACHLOR COMPLEXITY OF USE AND MISUSE/MISAPPLICATION

For the purpose of assessing the human health and environmental risks of heptachlor, as discussed in this Registration Standard, EPA has assumed the proper use of heptachlor as a termiticide in accordance with label directions. However, reports to EPA have indicated a significant incidence of misuse and misapplication of heptachlor by professional and non-professional applicators employing soil injection and trenching methods.

The data indicate that applicators have inadvertently contaminated structures while applying heptachlor into prepared injection holes or trenches. These types of incidents underscore the need for applicators to be knowledgeable about building construction elements or anomalies. When applying heptachlor by soil treatment methods, it is generally necessary for applicators to take appropriate site-specific precautions. Different types of house construction (rubble foundations, crawl spaces, etc.) require different methods of treatment as well as techniques to avoid contamination of ventilation systems and other vulnerable areas (electrical conduits, heating pipes or lines, water supplies, etc.).

From an economic standpoint, ignorance or insufficient training regarding these factors can result in significant property damage. Reports indicate that such damage may involve extensive costs, in some instances requiring new ventilation systems, decontamination of drinking water, or replacement of carpeting and wall paneling in the contaminated area. From a health risk standpoint, contaminated air systems may result in unnecessarily high, long-term human exposure to heptachlor over and above levels that may be anticipated on the basis of controlled ambient air exposure monitoring. Additionally, the improper use of heptachlor has the potential to result in environmental contamination. For these reasons, considered together with the toxic properties of heptachlor and its potential to persist and bioaccumulate in the environment in its epoxidized form, EPA is requiring that heptachlor be restricted for retail sale to and use by Certified Applicators or persons under their direct supervision, as specifically defined in Section IV. A.2. of this Registration Standard.

It has been six years since EPA initiated the Label Improvement Program (LIP) for termiticides. The LIP was designed to improve pesticide labels in order to protect health and environmental safety and to assist the user and the enforcer to clearly understand what practices constitute legal use. The Agency now believes there is a need to upgrade the termiticide LIP regarding use instructions and precautionary statements to further minimize potential exposure to both homeowners and commercial applicators (i.e. retreatment restrictions and prohibition against use in plenum housing). The required label changes are prescribed in detail in Section IV.D (Required Labeling).

E. TOLERANCES AND ACTION LEVELS

Prior to the cancellation of all food and feed uses of heptachlor, tolerances for total residues of heptachlor and its epoxidation product, heptachlor epoxide, resulting in or on raw agricultural commodities from application of heptachlor were established as listed in 40 CFR 180.104 and 40 CFR 180.319. As noted in Section I.B of this Registration Standard, tolerances were not revoked concurrently with these cancellations because of heptachlor's slow rate of degradation and its persistence in the environment. However, EPA is now proceeding to revoke these tolerances in accordance with a 1982 agreement among EPA, FDA, and USDA, entitled "Policy Statement on the Revocation of Tolerances for Cancelled Pesticides" (47 FR 42956). This policy statement describes when and how tolerances will be revoked and action levels substituted for certain pesticides for which registered uses have been cancelled, and what factors will be considered in recommending action levels for pesticide residues occurring in food and animal feed commodities as a result of environmental contamination.

The revocation of tolerances supporting previous agricultural uses of heptachlor, and EPA's recommendations concerning action levels to replace these tolerances, is independent of this Registration Standard, and is being completed through formal rulemaking. The proposed rule to revoke all tolerances for residues of heptachlor under the Federal Food, Drug, and Cosmetic Act (FFDCA) was published December 11, 1985 (50 FR 50643) and public comment was invited. The final rule is scheduled for publication in the Federal Register in early 1987.

In addition to action levels to replace existing tolerances, EPA is recommending that all existing action levels be lowered to 0.02 ppm, with the exception of fish and shellfish to be retained at 0.3 ppm, and fat of meat from goats, cattle, hogs, horses, sheep, poultry and rabbits to be lowered from 0.3 ppm to 0.2 ppm. When additional data on current residue levels and fish consumption patterns are collected and analyzed by the Agency, EPA will reassess the present 0.3 ppm action level for fish and shellfish.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

Based on review and evaluation of all available data on heptachlor, the Agency has made the following determinations. Refer to Section IV.D. for specific language for label revisions.

1. EPA is currently evaluating the potential human health risks of (1) non-oncogenic chronic liver effects, and (2) oncogenic effects to determine whether additional regulatory action on heptachlor may be warranted.

   Rationale: EPA has received and evaluated preliminary results covering the first 90 days of a one-year indoor air monitoring study. The Agency found significant problems with the study and is working closely with the registrant to resolve the issues. The Agency will conduct a quantitative risk assessment when adequate validation data have been received and evaluated. EPA is concerned about the potential human health risks of heptachlor based on limited literature values for ambient air levels of heptachlor/chlordane in treated homes, coupled with heptachlor epoxide's extremely low PADI (1.3 x 10^{-5} mg/kg/day), and high cancer potency value ($Q^{*-1}= 9.1$ per mg/kg/day). EPA will be considering the results of the indoor air monitoring study, together with the evidence on the oncogenicity of heptachlor to determine whether human exposure to heptachlor may be posing a human health risk of regulatory concern.

2. In order to meet the statutory standard for continued registration, the Agency has determined that the retail sale and use of all end-use products containing heptachlor for termite control must be restricted to Certified Applicators or persons under their direct supervision, as specifically defined in the "Restricted Use Pesticide" label provision prescribed by EPA in Section IV.D. of this Registration Standard. As this label provision states, direct supervision of a Certified Applicator means one of two options regarding the use of heptachlor products:

   (a) the actual physical presence of the Certified Applicator at the application site during application, or (b) if the Certified Applicator is not physically present at the site, each uncertified applicator must have completed a State approved training course in termiticide application meeting minimal EPA training requirements and be registered in the State in which the applicator is working after a determination by the State of the individual's competence.

If States elect to implement the second option provided on the label, then specific, minimum training and registration criteria set forth by EPA must be adopted and followed by the State.

Training may be conducted by industry or other groups provided minimum EPA and State training standards are met. Technicians will not be considered competent until the State has determined that they are competent. Any necessary enabling State legislation and/or regulations will have to be in place before EPA will approve a State program. Before States may exercise this option, a description of their program, including training requirements, approach for determining competence, and registration process must be submitted to and approved by EPA under guidance established by the Agency's Pesticide Certification and Training Office. States may choose to adopt measures more restrictive than those set forth in this Registration Standard.

A State desiring to establish a registration program for termiticide technicians must present to the Agency for approval a program and plan consisting of at least the following elements:

- Training to include basic information on:

a. Application equipment, rates of application, and mixing, loading, and handling procedures for heptachlor products;

b. Detailed information on construction elements of the structures likely to be encountered when applying heptachlor and the appropriate and proper application methods for each construction element;

c. Operation, care, and maintenance of application equipment and protective equipment and apparel;

d. Comprehension of label information and restrictions;

e. Environmental and human health consequences of termiticide misuse including the acute and chronic health hazards of heptachlor, potential impact on water supplies, and potential impacts on the environment and treated structures;

f. Techniques for decontamination, if possible, of structures should an accident or misapplication occur;

g. Safety in storage and disposal of heptachlor, heptachlor product containers, unused heptachlor solution, and contaminated protective equipment and clothing;

h. Emergency procedures, should an accident occur, for the protection of the applicator and the occupants of the treated structure, and warning signs of misapplication that would be useful to communicate to the occupants.

Training developed by industry or others in support of this second option shall be submitted for review and approval to appropriate State regulatory agencies in States which have a termiticide technician training registration program. Such training materials or programs must include at least the above listed elements plus any other requirements which a State might specify.

- Competence demonstrated by: a process or method whereby the State can determine the person is competent to apply the product by examination or other methods acceptable to EPA.

- Registration by: a system of registration with the State after the applicant has demonstrated to the State a satisfactory level of competence in termiticide application.

Rationale: As stated in 40 CFR 162.11(c)(4), pesticide products may be classified for restricted use if there is evidence that the product "may pose a serious hazard to man or the environment which can reasonably be prevented by classification for restricted use." The Agency considers the subterranean termiticide application to be complex and require a great deal of specialized knowledge. Data available to EPA indicate recurring misuse and misapplication of heptachlor termiticide products by pest control operators. In view of the potential health hazards associated with exposure to heptachlor, the Agency is concerned about long-term and acute exposures which may result from the improper use of heptachlor. The Agency is especially concerned about the contamination of air systems in structures improperly treated for termite control, since such contamination may result in unnecessarily high, long-term exposure to heptachlor over and above levels that may be anticipated following proper applications. In addition, the misuse of heptachlor has the potential to result in environmental contamination.

For these reasons, the Agency believes that the statutory standard for registration can be met only if these products are restricted for sale to and use by Certified Applicators or persons under their direct supervision, as defined above and in the "Restricted-Use Pesticide" label provision prescribed in Section IV.D. Several States have already restricted the use of heptachlor. By presenting two options for compliance with the restricted use requirement for heptachlor, it is EPA's intent to ensure that heptachlor is competently applied: either under the immediate, physical supervision of a Certified Applicator who can direct the implementation of site-specific precautions as appropriate (Option 1); or, if a Certified Applicator is not physically present, each State-registered technician working at the site will have demonstrated competence to safely conduct termiticide applications, following completion of a training course in termiticide application administered by the State in which he or she is working (Option 2). The two options are intended to offer States some administrative discretion in regulating professional pest control operations under their jurisdiction. At the same time, EPA believes that either option will serve to upgrade competence among users of heptachlor. EPA believes that, where a Certified Applicator is not physically present, trained technicians are less likely to misuse or misapply heptachlor. The minimum training and registration criteria set forth in this Registration Standard for State programs are intended to ensure that all users of heptachlor who are not Certified Applicators have demonstrated competence in all aspects of termiticide application ranging from comprehension of the importance of label precautions to practical knowledge of emergency procedures in the event that an accident should occur.

3. In order to meet the statutory standard for continued registration, the Agency has determined that heptachlor product labels must be revised to provide specific disposal procedures.

   Rationale: Heptachlor products are acutely hazardous when discarded, and improper disposal of excess pesticide, spray mixture, or rinsate may result in risks to human health and/or environmental contamination. Heptachlor is very highly toxic to fish and freshwater invertebrates. It is therefore imperative that effluent containing heptachlor not be improperly discharged into surface waters or sewer systems.

4. In order to meet the statutory standard for continued registration, the Agency has determined that heptachlor products must bear fish and wildlife toxicity warnings.

   Rationale: Labeling requirements are imposed since available data indicate that heptachlor is very highly toxic to warm- and cold-water fish species, freshwater invertebrates, and birds.

5. A special monitoring study is required to evaluate whether and to what extent surface water contamination may be resulting from the use of heptachlor as a termiticide.

   Rationale: Heptachlor and its degradate heptachlor epoxide are persistent in the environment and can bioaccumulate in fish and fresh-water invertebrates. Human dietary exposure to heptachlor may occur through consumption of contaminated drinking water and fish. In addition, heptachlor is potentially very highly toxic to fish and freshwater invertebrates. The physical and chemical properties of heptachlor are similar to the properties of chlordane, a cyclodiene termiticide which has been found in fish at levels exceeding the FDA action level at various urban aquatic sites in in·Iowa, Missouri and Nebraska. Preliminary evidence indicates that the source of contamination may be the termiticidal use of chlordane. Both chemicals also have similar application patterns, and it is reasonable to expect that they may have comparable behavior patterns in the environment.

   The Agency is therefore requiring a study, in which sump pump, drainage tiles and sanitary sewer water, draining from home foundations known to have been properly treated with heptachlor, are sampled for heptachlor residues. Based on the results of this study, additional regulatory action may be warranted.

6. The Agency is requiring the submission of applicator exposure data from dermal and respiratory routes of exposure.

   Rationale: Additional data are needed to determine whether exposure to applicators during application of heptachlor products may be posing significant health risks. Registrants are referred to Subdivision U of the Pesticide Assessment Guidelines for acceptable exposure monitoring methodology. This Guideline document is publicly available through the National Technical Information Service (NTIS), Springfield, Virginia 22151 (telephone: 703-487-4650). Registrants must submit appropriate protocols for these exposure studies within 90 days.

7. In order to meet the statutory standard for continued registration the Agency has determined that heptachlor product labels must contain a prohibition against application to plenum houses (houses where the crawlspace beneath the building is used to circulate heated or cooled air without ductwork).

   Rationale: This restriction is necessary to guard against potentially high levels of exposure. Information indicates that application to these houses can result in very high indoor air levels.

8. The Agency is requiring a new two-year rat oncogenicity study using heptachlor epoxide. Further, examination of eye tissue from this oncogenicity study is required to evaluate the potential for heptachlor to cause optic neuritis in humans as a result of termiticide treatment of homes.

   Rationale: The available oncogenicity test data for rats are inconclusive. Therefore, a new two-year rat oncogenicity study is required to characterize the oncogenic potential of heptachlor epoxide in this species. The Agency was recently appraised of three reported cases of optic neuritis in humans associated with termiticidal application of a related cyclodiene pesticide, chlordane. To determine whether this health effect is significant and whether heptachlor plays a role, the registrant must have eye tissue from the rat oncogenicity study analyzed by neuropathologists specializing in optic tissue pathology.

9. Special product-specific subacute inhalation testing is required to evaluate the respiratory hazards to humans in structures treated with termiticide products containing heptachlor.

   Rationale: The Agency has received reports from individuals complaining of upper respiratory problems associated with termiticidal application of related cyclodiene pesticides. To investigate the extent of the problem and whether heptachlor plays a role, the Agency is requiring additional short-term inhalation studies of two-week duration using guinea pigs or rats to further delineate the irritative capabilities to mucous membranes of heptachlor, formulation solvents, and the combination (i.e. formulated products.).

10. A rat inhalation study must be conducted in which the test duration is one-year and the lowest dose tested is the NAS guideline as requested in the 1984 Data Call-In Notice.

Rationale: The rat inhalation study submitted by the registrant in response to the 1984 Data Call-In (DCI) Notice was considered invalid by the Agency because the lowest dose tested was higher than the NAS guideline level, and because the study centered on the use of chlordane with only about 10 percent of the test material being heptachlor. The DCI requirement was for a 90-day test duration; a one-year exposure period is now required because the longer exposure period should more likely reflect typical human exposure resulting from termiticide treatment of homes.

11. Special indoor air monitoring studies are required to support heptachlor's use on structural wood (above ground); its perimeter surface treatment in human dwellings for termite control; and its subsurface injection of heptachlor-containing cartridges for termite control.

Rationale: In 1984, the Agency issued a Data Call-In Notice to registrants of products containing heptachlor requiring a monitoring study of heptachlor air levels in homes of various construction types treated with heptachlor for subterranean termite control. The requirement was imposed to provide data to estimate human exposure and to assess the risks to humans associated with soil treatment use of heptachlor. A study is currently underway. The Agency is also concerned over the potential health risks posed by the use of heptachlor above ground on structural wood (i.e. sills, joists, headers, plates, cuts or studs, and other structural members used in the framing of a house), and as a perimeter surface treatment in human dwellings (a special local need registration). For this reason, the Agency is requiring indoor air monitoring of dwellings treated in accordance with current label restrictions to support each of these unique use patterns.

12. The Agency is requiring that the heptachlor five percent granular product registered for control of fire ants in buried pod mounted electric power transformers and cable television and telephone pedestals be classified as a restricted-use product.

Rationale: Data on applicator exposure resulting from this unique use pattern for heptachlor are lacking and therefore the Agency is unable to evaluate the potential risks to applicators applying this product to electrical power transformers and telephone pedestals. Restricted-use classification is required as an interim risk reduction measure until applicator exposure data have been received and evaluated.

13. In order to meet the statutory standard for continued registration the Agency has determined that the existing use directions under the current termiticide LIP for heptachlor product labels must be clarified in order to further minimize human exposure and avoid contamination of the environment.

Rationale: Under the current termiticide LIP questions have been raised regarding existing use directions pertaining to soil treatment. Information indicates that certain treatment procedures and clarification to accommodate technical and safety aspects of termite control and minimize exposure to homeowners and applicators is necessary. Such revisions and precautions make the treatment instructions more clear, minimize misapplication and ensure compliance.

14. While data gaps are being filled, currently registered manufacturing use products (MPs) and end-use products (EPs) containing heptachlor may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency may elect not to cancel or withhold registration even though data are missing or are inadequate (see FIFRA sec. 3(c)(2)(B) and 3(c)(7)). Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary.

15. The Agency has identified certain data that will receive priority review when submitted to the Agency.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

§158.135 Toxicology

82-4	Subchronic Inhalation - Rats (one-year) - Rats or Guinea Pigs (two-weeks)
83-1	Chronic Toxicity - Rodents and Non-rodents
83-2	Oncogenicity - Rats
83-3	Teratogenicity - Rat and Rabbit
84-2, 3,4	Mutagenicity
	Special Test for optic neuritis

§158.125 Environmental Fate

161-1	Hydrolysis
161-2	Photodegradation in Water
162-1	Aerobic Soil Metabolism
162-2	Anaerobic Soil Metabolism
162-4	Aerobic Aquatic Metabolism
163-1	Leaching and Adsorption/Desorption
164-2	Soil Dissipation
	Surface Water Monitoring Study
	Applicator Exposure Studies
	Indoor Air Monitoring Studies

§158.145 Ecological Effects

71-1 Acute Avian Oral Toxicity

§158.120 Product Chemistry

All requirements

B. CRITERIA FOR REGISTRATION

This Standard covers both manufacturing-use products (MPs) and end-use products (EPs) containing heptachlor[4/]. Registrants of heptachlor products must comply with all terms and conditions described in this section, including submission of an up-to-date Confidential Statement of Formula, submission of revised labeling, commitment to fill data gaps on the schedule specified by the Agency and, when applicable, offer to pay compensation as required by 3(c)(1)(D) and 3(c)(2)(D) of the FIFRA.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard - Each product proposed for registration or reregistration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active and intentionally added inert ingredients which will be present in the product. The active ingredient in any new product must be substantially similar to that in currently registered heptachlor products.

2. Acute Toxicity Limits - The Agency will consider registration of any product in any Toxicity Category provided the product labeling bears appropriate precautionary statements.

3. Use Patterns - Manufacturing-use products containing heptachlor must be labeled for formulation into end-use products only for subterranean termite control, above ground wood preservative treatment for the control of wood-destroying insects, or for fire ant control in buried cable closures. The EPA Compendium of Acceptable Uses, Appendix III, lists the approved application rates and methods of application.

[4/] The Agency considers all currently registered end-use products containing heptachlor to be sole active ingredient formulations. The Agency does not consider solvents or diluents to be insecticidal and therefore, must be declared as inert ingredients.

D. REQUIRED LABELING

All manufacturing-use products (including formulation intermediates) and end-use products must bear appropriate labeling as specified in 40 CFR 162.10, PR Notices 83-2 and 83-3, and as indicated in this Registration Standard (as appropriate). No end-use or manufacturing-use product containing heptachlor may be released for shipment by a registrant or producer of that product 12 months after the registrant's or producer's receipt of this Registration Standard, unless the product bears an EPA-approved amended label which complies with this Registration Standard.

No end-use or manufacturing-use product containing heptachlor may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person 24 months after issuance of this Registration Standard, unless the product bears an EPA-approved amended label which complies with this Registration Standard.

1. All Products - All products must bear appropriate labeling as specified in 40 CFR 162.10. Appendix II contains information on labeling requirements. The following pesticide disposal statement must appear on all labels:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

2. Manufacturing-use Products - All manufacturing-use products must bear the following statements:

> "For formulation into end-use insecticide products intended only for subterranean termiticide use, above-ground structural wood treatment for control of termites and other wood-destroying insects, and for fire ant control in buried cable closures."

> "This pesticide is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

"The use of this product may be hazardous to your health. This product contains heptachlor, which has been determined to cause cancer and adverse liver effects in laboratory animals."

"Mixer/loaders must wear goggles or a face shield, chemical-resistant apron, long-sleeved shirt and long pants, or coveralls, and unlined, mid-forearm to elbow length chemical-resistant gloves when mixing, loading, or otherwise handling concentrate."

3. End-use Products - Labels for all end-use products must bear the following statements:

"This pesticide is toxic to fish and wildlife. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of waste."

"Applicators must wear water resistant hat, lightweight protective suit or coveralls, unlined chemical-resistant gloves (natural rubber, neoprene, or polyethylene), and unlined lightweight boots. MSHA/OSHA approved respirators are required for applications in enclosed areas such as crawl spaces. Mixer/loaders must wear goggles or a face shield, chemical-resistant apron, long-sleeved shirt long pants, or coveralls, and unlined, mid-forearm to elbow length chemical-resistant gloves when mixing, loading, or otherwise handling the concentrate."

4. End-use Products Labels for end-use products bearing use directions for subterranean termite control and above-ground structural wood treatment for control of termites and other wood-destroying insects must be revised to include the following statements:

"Do not apply heptachlor in or around poultry houses, barns, silos, milk houses, or other structures or enclosures where livestock or poultry is held, or where food/feed is stored, prepared or processed."

"RESTRICTED-USE PESTICIDE

The use of this product may be hazardous to your health. This product contains heptachlor, which has been determined to cause cancer and adverse liver effects in laboratory animals. This pesticide persists in the environment and bioaccumulates in living organisms. Risks can be reduced by closely following all use directions and precautions, and by wearing the protective clothing specified elsewhere on this label. Treated buildings may be contaminated, resulting in hazards to the health of occupants if this product is not properly applied and used only for the purpose stated on the label.

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification. For the purposes of this product, direct supervision of a Certified Applicator means either: 1) the actual physical presence of the Certified Applicator at the application site during application, or 2) if the Certified Applicator is not physically present at the site, each uncertified applicator acting under instructions and control of the Certified Applicator who is available if and when needed, must have completed a State approved training course which meets EPA minimal requirements in termiticide application and must be registered for termiticide application in the State in which the uncertified applicator is working."

"Do not apply heptachlor to plenum houses (houses where the crawlspace beneath the building is used to circulate heated or cooled air without ductwork)."

Labeling for end-use products bearing use directions for subterranean termite control and above-ground structural wood treatment for control of termites and other wood-destroying insects must be revised to include the following information. (Note: The following is a revision of the current LIP use directions. Each revision/change to the current LIP is italicized for easy reference.)

GENERAL INFORMATION ON THE USE OF THIS PRODUCT

Chemicals for soil treatment are used to establish a barrier against termites. The chemical emulsion must be adequately dispersed in the soil to provide a barrier between the wood in the structure and the termite colonies in the soil.

It is necessary for the effective use of this product that the service technician be familiar with current control practices including trenching, rodding, subslab injection and low-pressure applications. These techniques must be correctly employed to prevent or control infestations by subterranean termites such as Reticulitermes, Zootermopsis, Heterotermes, and Coptotermes. Choice of appropriate procedures should include consideration of such variable factors as the design of the structure, existence of air circulation in subfloor crawlspace, watertable, soil type, soil compaction, grade conditions, and the location and type of domestic water supplies *and drainage systems.* The biology and behavior of the termite species involved are important factors to be known, as well as suspected location of the colony and severity of the infestation within the structure to be protected.

All nonessential wood and cellulose-containing materials, including scrap wood and form boards, should be removed from around foundation walls, crawlspaces, and porches. *Effective termite control also includes elimination of termite access to moisture by recommending repair of faulty construction, grade, and/or plumbing.*

For advice concerning current control practices with relation to the specific local conditions, consult resources in structural pest control and the State regulatory agency.

SUBTERRANEAN TERMITE CONTROL
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. *This product may not be used against any pests not named on the label. Apply only to establish subsurface termite control barriers specified on product labeling.*

Contamination of public and private water supplies must be avoided by following these precautions: Use antibackflow equipment or procedures to prevent siphonage of pesticide back into water supplies. Do not treat soil beneath structures that contain cisterns or wells. Do not treat soil that is water saturated or frozen. Consult State and local specifications for recommended distances of treatment areas from wells. *If no State or local government recommendations are available, refer to Federal Housing Administration specifications for further guidance.*

PRECONSTRUCTION SUBTERRANEAN TERMITE TREATMENT

Effective preconstruction subterranean termite control requires the establishment of an unbroken vertical and/or horizontal chemical barrier between wood in the structure and the potential or existing termite colonies in the soil. To meet FHA termite-proofing requirements, follow the latest edition of the Housing and Urban Development (HUD) Minimum Property Standards.

Use a ____ water emulsion for subterranean termites. Mix ____ gallon of (product name) in ____ gallons of water to produce a water emulsion.

Do not apply to any area intended as a plenum airspace. Check with the builder or contractor to determine if the design of the structure includes a plenum airspace.

HORIZONTAL BARRIERS

Before footings are poured, horizontal barriers may be established in footing trenches. Then, after interior grading is completed and prior to the pouring of concrete slabs, horizontal barriers may be established on soil that will be covered by floors, entrance platforms, or porches, and in other critical areas that will be covered by construction. To produce a horizontal barrier, apply the emulsion at the rate of 1 gallon per 10 square feet to fill dirt. If fill is washed gravel or other coarse material, apply at 1 1/2 gallons per 10 square feet.

- *It is important that the emulsion reaches the soil.*
- *Applications shall be made with low pressure (less than 50 psi at the nozzle) using a coarse-spray nozzle when establishing horizontal barriers.*
- *If concrete slabs cannot be poured over soil the same day it has been treated, a waterproof cover such as polyethylene sheeting should be placed over the soil to prevent erosion. This is not necessary if foundation walls have been installed around the treated soil.*

VERTICAL BARRIERS

After the foundation walls have been poured or built, vertical barriers may be established around the perimeters of floating or supported slabs, around utilities penetrating the slab, and in other critical areas. After the final exterior grading is completed, vertical barriers may be created in back-filled soil *against foundation walls. To produce a vertical barrier, apply the emulsion at the rate of 4 gallons per 10 linear feet per foot of depth from grade to the top of the footing.*

- Rodding and/or trenching applications should not be made below the top of the footing *except when the footing is exposed at or above grade. Special care should be taken to avoid soil washout around the footing.*
- Trenches need not be wider than 6 inches.
- When rodding, it is important that emulsion reaches the footing. Rodholes should be spaced to provide a continuous barrier.
- Emulsion should be mixed with the soil as it is being replaced in the trench. Cover treated soil with a layer of untreated soil.

HOLLOW MASONRY UNITS OF FOUNDATION WALLS

In preconstruction situations in which application is not made to soil prior to pouring the footing, treatment may be made through masonry voids to establish a continuous chemical barrier at the top of the footing. Apply at the rate of 2 gallons of emulsion per 10 linear feet of footing.

Do not treat in this manner through voids in walls constructed *on* *interior slabs such as basement floors.*

CRAWLSPACES

For crawlspaces, vertical barriers may be established using a rate of 4 gallons of emulsion per 10 linear feet per foot of depth from grade to the top of the footing. Application may be made by rodding and/or trenching to the footing. *If the footing is exposed at or above grade, application should be made with special care to avoid washout around the footing. Treatment should include both sides of foundation and around all piers and pipes extending from the soil. To avoid volatilization into air within the structure, do not make an overall broadcast application to areas intended to be crawlspaces, apply by rodding and/or trenching.*

- Rodholes should be spaced to provide a continuous chemical barrier.
- Trenches need not be wider than 6 inches nor below the footing. The emulsion should be mixed with the soil as it is being replaced in the trench. Cover the treated soil

with a layer of untreated soil. *Moisture barriers such as polyethylene sheeting may be used in addition to the untreated soils.*

MONOLITHIC SLABS

In the case of a single-pour monolithic slab that does not have a separate foundation or footing, an overall horizontal barrier should be created before the concrete is poured using a rate of 1 gallon of emulsion per 10 square feet. If fill is washed gravel or other coarse material, apply at the rate of 1 1/2 gallons per 10 square feet. Critical areas beneath the slab such as utility pipe entries may be treated at the rate of 4 gallons per 10 linear feet around the pipe.

Exterior vertical barriers should be created after the concrete has been poured and final grade established. Apply the emulsion at the rate of 4 gallons per 10 linear feet per foot of depth to the bottom of the concrete.

POSTCONSTRUCTION TREATMENTS

Use a ____ water emulsion for subterranean termites. Mix ____ gallon of (product name) in ____ gallons of water to produce a ____ water emulsion.

Postconstruction applications may be made by injection, rodding and/or trenching with pressures less than 25 psi at the nozzle. *To avoid volatilization into the air within the structure, do not make an overall broadcast application of this product in a crawl-space. Rodholes or trenches should not extend below the footing because of the possibility of soil washout by the emulsion.*

Do not apply this product to the soil beneath a plenum airspace.

Do not apply emulsion until location of heat or air conditioning ducts, vents, water and sewer lines, and electrical conduits are known and identified. *Do not apply this product to soil beneath slabs with subslab or intraslab ducting until ducts are permanently plugged.*

CONCRETE SLABS

Vertical barriers may be established by subslab injection inside and rodding and/or trenching outside at the rate of 4 gallons of emulsion per 10 linear feet. Injectors should not extend beyond the tops of the footings.

Treat along the outside of the foundation and where necessary just beneath the slab on the inside of foundation walls. Treatment with a layer of untreated soil. *Moisture barriers such as polyethylene sheeting may be used in addition to the untreated soils.*

MONOLITHIC SLABS

In the case of a single-pour monolithic slab that does not have a separate foundation or footing, an overall horizontal barrier should be created before the concrete is poured using a rate of 1 gallon of emulsion per 10 square feet. If fill is washed gravel or other coarse material, apply at the rate of 1 1/2 gallons per 10 square feet. Critical areas beneath the slab such as utility pipe entries may be treated at the rate of 4 gallons per 10 linear feet around the pipe.

Exterior vertical barriers should be created after the concrete has been poured and final grade established. Apply the emulsion at the rate of 4 gallons per 10 linear feet per foot of depth to the bottom of the concrete.

POSTCONSTRUCTION TREATMENTS

Use a ____ water emulsion for subterranean termites. Mix ____ gallon of (product name) in ____ gallons of water to produce a ____ water emulsion.

Postconstruction applications may be made by injection, rodding and/or trenching with pressures less than 25 psi at the nozzle. *To avoid volatilization into the air within the structure, do not make an overall broadcast application of this product in a crawl-space. Rodholes or trenches should not extend below the footing because of the possibility of soil washout by the emulsion.*

Do not apply this product to the soil beneath a plenum airspace.

Do not apply emulsion until location of heat or air conditioning ducts, vents, water and sewer lines, and electrical conduits are known and identified. *Do not apply this product to soil beneath slabs with subslab or intraslab ducting until ducts are permanently plugged.* Surface application is prohibited. (italics)

CONCRETE SLABS

Vertical barriers may be established by subslab injection inside and rodding and/or trenching outside at the rate of 4 gallons of emulsion per 10 linear feet. Injectors should not extend beyond the tops of the footings.

Treat along the outside of the foundation and where necessary just beneath the slab on the inside of foundation walls. Treatment may also be required just beneath the slab along both sides of interior footing-supported walls, one side of interior partitions, and along cracks and expansion joints. *Horizontal barriers may be established where necessary by long rodding or by a grid pattern injection using a rate of 1 to 1 1/2 gallons of emulsion per 10 square feet depending on fill type and condition.*

- Drill holes in the slab about 12 to 36 inches apart to provide a continuous chemical barrier.

- Where necessary, drill through the foundation walls from the outside and *inject* the emulsion just beneath the slab either along the inside of the foundation or along cracks, expansion joints, and other critical areas.

- For shallow foundations 1 foot or less, dig a narrow trench approximately 6 inches wide along the outside of the foundation walls. Do not *trench* below the bottom of the foundation. The emulsion should be applied to the trench and the soil at 4 gallons per 10 linear feet as the soil is replaced in the trench. Cover the treated soil with a layer of untreated soil.

- For foundations deeper than 1 foot follow rates for basements.

HOLLOW MASONRY UNITS OF FOUNDATION WALLS

Treatment may be made through masonry voids to establish a continuous chemical barrier at the top of the footing. Apply at the rate of 2 gallons of emulsion per 10 linear feet of footing. Where this treatment is necessary, access holes must be drilled below the sill plate and should be through a lower mortar joint. Before treatment through basement walls, seal the interior wall and floor expansion joint with mortar, caulk, waterproofing material, or similar impervious sealant. Also, seal openings at the top of the foundation wall. Do not treat in this manner through voids in walls constructed on interior slabs such as basement floors.

BASEMENTS

For basements and slab foundations that extend more than 1 foot below grade, vertical barriers may be applied at a rate of 4 gallons of emulsion per 10 linear feet per foot of depth from grade to the top of the footing. Treat the outside of the foundation by trenching and/or rodding. Subslab injection may be necessary along the inside of foundation walls, along cracks, along partitions, around sewer pipes, conduits, and piers, and along both sides of interior footing-supported walls.

CRAWLSPACES

In crawlspaces, vertical barriers may be applied at the rate of 4 gallons of emulsion per 10 linear feet per foot of depth from grade to top of footing. Application may be made by rodding and/or trenching.

Do not apply this product to the soil beneath a plenum airspace.

To avoid volatilization into air within the structure, do not make an overall broadcast application of this product in a crawlspace: apply by rodding and/or trenching. Rodholes or trenches should not extend below the footing. Treat both sides of foundation and around all piers and pipes.

- Rodholes should be spaced to provide a continuous chemical barrier.
- Trenches need not be wider than 6 inches nor below the footing. The emulsion should be mixed with the soil as it is replaced in the trench. Cover the treated soil with a layer of untreated soil. *Moisture barriers such as polyethylene sheeting may be used in addition to the untreated soil.*
- *If it is necessary to make an overall barrier under soil in a crawlspace, this treatment may only be made by injecting the emulsion several inches below the soil surface.*
- *It should be recommended that inadequately ventilated crawlspaces be brought into compliance with FHA Minimum Property Standards specifying 1 square foot of ventilator opening per 150 square feet of crawlspace area.*

EXCAVATION TECHNIQUE

If treatment must be made in difficult situations such as near wells or cisterns, along faulty foundation walls, and around pipes and utility lines which lead downward from the structure, application may be made in the following manner:

- *Trench and remove the soil to be treated onto heavy plastic sheeting or similar liner.*
- *Treat the soil at the rate of 4 gallons of emulsion per 10 linear feet per foot of depth of the trench. Mix the emulsion thoroughly into the soil taking care to prevent liquid from running off the liner.*

- *After the treated soil has dried adquately, replace the soil in the trench and cover with a layer of untreated soil.*

Prior to using this technique near wells or cisterns, consult State, local, or Federal regulatory agencies for information regarding approved treatment practices in your area.

AFTER TREATMENT

Before leaving the job site, securely plug all holes drilled in construction elements of commonly occupied areas of structures, including unfinished basements, enclosed porches, garages, and workshops.

RETREATMENT

Retreatment for subterranean termites should only be made when there is evidence of reinfestation subsequent to the initial treatment, or there has been a disruption of the chemical barrier in the soil due to construction, excavation, landscaping, etc. Retreatment should be made as a spot application to these areas.

Retreatments may be made to critical areas in accordance with the application techniques described above. This application should be made as a spot treatment to these areas. Routine retreatment of the entire premises should be avoided.

5. End-use Products Labels for the end-use product (5%G) intended for fire ant control in buried cable closures must bear the following statement:

> "Restricted Use Pesticide
>
> The use of this product may be hazardous to your health. This product contains heptachlor, which has been determined to cause cancer and adverse liver effects in laboratory animals. This pesticide persists in the environment and bioaccumulates in living organisms. Risks can be reduced by following all use directions and precautions, and by wearing the protective clothing specified elsewhere on this label.
>
> For retail sale to and use only by Certified Applicators or persons under their direct supervision, and only for those uses covered by the Certified Applicator's certification."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B.[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A and labeling requirements specified for manufacturing use products in Section IV.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

C. End use products containing this pesticide as the sole active ingredient* are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

* solvents or diluents must be declared as inerts. The Agency does not have data indicating that these solvents are insecticidal.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those Data requirements.

c. The labeling requirements specified for end use products specified in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients. (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from (or are not specified in) either EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing and await EPA approval, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

F. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made before the deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring.

EPA will view failure to request an extension before the response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. Time extensions may be considered when joint data development is planned, or when the Agency must approve a new or modified protocol before the study can be begun.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

G. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section IV.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options IV.D.1. (submit data) or IV.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing Heptachlor as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4), attached separately.

c. Formulator's Exemption Statement, if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D) Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any required product-specific data (See Table B).

b. Five (5) copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

c. Product Specific Data Report.

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing Heptachlor in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4), attached separately.

c. Formulator's Exemption Statement, if applicable.

2. Within 9 months from receipt of this document you must submit five (5) copies of draft labeling.

3. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing Heptachlor alone[6]/ or in combination with other active ingredients

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4), attached separately.

c. Formulator's Exemption Statement, if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

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[6] The Agency considers all currently registered end-use products to be sole active ingredient formulations. The Agency does not consider solvents or diluents to be insecticidal, and therefore, must be declared as inerts.

b. Product Specific Data Report, if Table C lists required product-specific data.

c. Five copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

E. Addresses

The required information must be submitted to the following address:

George LaRocca
Product Manager 15
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product
N/A = Data requirement not applicable to the use pattern

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.
4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the receipt date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR HEPTACHLOR

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1/]	Bibliographic Citation [1/]	Must Additional Data be Submitted?	Timeframe for Submission[2/]
§158.120 Product Chemistry						
Product Identity						
61-1 - Product Identity and Disclosure of Ingredients	TGAI	B,H,I			Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	B,H,I			Yes	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	B,H,I			Yes	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	B,H,I			Yes	12 Months
62-2 - Certification of Limits	TGAI	B,H,I			Yes	12 Months
62-3 - Analytical Methods to Verify Certified Limit	TGAI	B,H,I			Yes	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	B,H,I			Yes	6 Months
63-3 - Physical State	TGAI	B,H,I			Yes	6 Months
63-4 - Odor	TGAI	B,H,I			Yes	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR HEPTACHLOR

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation 1/	Must Additional Data be Submitted?	Timeframe for Submission2/
§158.120 Product Chemistry (continued)						
Physical and Chemical Characteristics (continued)						
63-5 - Melting Point	TGAI	B,H,I			Yes	6 Months
63-6 - Boiling Point	TGAI	B,H,I			No3/	
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	B,H,I			Yes	6 Months
63-8 - Solubility	TGAI or PAI	B,H,I			Yes	6 Months
63-9 - Vapor Pressure	PAI	B,H,I			No4/	
63-10 - Dissociation Constant	PAI	B,H,I			Yes	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	B,H,I			Yes	6 Months
63-12 - pH	TGAI	B,H,I			Yes	6 Months
63-13 - Stability	TGAI	B,H,I			Yes	15 Months (8 Months - Progress Report)
Other Requirements:						
64-1 - Submittal of Samples	TGAI, PAI	B,H,I			Reserved5/	

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

3/ Not required since heptachlor is a solid at room temperature.

4/ Not required because the melting point of the pure form is >30° C.

5/ If samples are needed, the Agency will request them.

TABLE A
GENERIC DATA REQUIREMENTS FOR HEPTACHLOR

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission 1/
§158.130 Environmental Fate (continued)						
163-2 - Volatility (Lab)	TEP	N/A				
163-3 - Volatility (Field)	TEP	N/A				
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	B,H	No		Yes	27 Months2/ (8 Months- Progress Report)
164-2 - Aquatic (Sediment)	TEP	H	No		Reserved3/	
164-3 - Forestry	TEP	N/A				
164-4 - Combination and Tank Mixes		N/A				
164-5 - Soil, Long-term	TEP	N/A				
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (confined)	PAIRA	N/A				
165-2 - Rotational Crops (field)	TEP	N/A				
165-3 - Irrigated Crops	TEP	N/A				
165-4 - In Fish	TGAI or PAIRA	H	No		Reserved3/	

TABLE A
GENERIC DATA REQUIREMENTS FOR HEPTACHLOR

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1/]
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	B,H	No		Yes	9 Months
Photodegradation						
161-2 - In Water	TGAI or PAIRA	H	No		Yes[3/]	9 Months
161-3 - On Soil	TGAI or PAIRA	N/A				
161-4 - In Air	TGAI or PAIRA	N/A				
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	B,H	No		Yes	27 Months[2/] (8 Months - Progress Report)
162-2 - Anaerobic Soil	TGAI or PAIRA	B,H	No		Yes[3/]	27 Months[2] (8 Months - Progres Report)
162-3 - Anaerobic Aquatic	TGAI or PAIRA	B,H	No		Reserved[3/]	
162-4 - Aerobic Aquatic	TGAI or PAIRA	H	No		Yes[3/]	27 Months[2] (8 Months - Progres Report)
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	B,H	No		Yes	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR HEPTACHLOR

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1]
§158.130 Environmental Fate (continued)						
165-5 - In Aquatic Nontarget Organisms	TEP	N/A				
MONITORING STUDIES:						
Water Monitoring Study	TEP	H,I	No		Yes[4]	15 Months (90 Days- Acceptable Protocol) (8 Months- Progress Report)
EXPOSURE STUDIES:						
Applicators	TEP	H,I	No		Yes[5]	6 Months (90 Days- Acceptable Protocol)
Residents- Indoor Air Monitoring Study- Velsicol's Ongoing Study	TEP	I	No		Yes[6]	(Final Report- February, 1987)
Residents- Indoor Air Monitoring Study- Above Ground Use in Structural Wood	TEP	I	No		Yes[7/8]	24 Months (90 Days- Acceptable Protocol) (8 Months- Progress Report)

1/ Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

2/ The first progress report is due 8 months after receipt of this Standard. Interim reports are due semi-annually thereafter.

3/ Because of the detection of residues of chlordane, a related cyclodiene pesticide, in urban water systems, presumably from termiticide uses, additional data requirements have been imposed, which will focus on the fate of heptachlor in the aquatic environment. These are: photodegradation in water, anaerobic soil metabolism and aerobic aquatic metabolism. Aquatic (sediment) dissipation and anaerobic aquatic metabolism data requirements are reserved pending results of the aerobic aquatic metabolism studies. Fish residue accumulation data are reserved pending the results of the octanol/water partition coefficient studies.

TABLE A

GENERIC DATA REQUIREMENTS FOR HEPTACHLOR

§158.130 Environmental Fate (continued)

4/ A special monitoring study is required, either prospective or retrospective; in which water from sanitary sewers, sumps, and drainage tiles, draining from home foundations treated with heptachlor, is sampled and analyzed for residues of heptachlor. An acceptable protocol must be submitted within 90 days of receipt of this Standard.

5/ Applicator exposure data must be submitted to support heptachlor's termiticide uses (subsurface and above ground) and it's use in buried cable closures for fire ant control. Acceptable protocols must be submitted within 90 days of receipt of this Standard.

6/ This requirement was originally imposed as part of the Agency's 1984 Termiticide Data Call-In program. This study currently in progress. Further testing may be required pending the results of this study.

7/ A one-year indoor air monitoring study is required to support registration of products registered for above ground use in structural wood. The study must be conducted in homes of various construction types, treated in accordance with label directions.

8/ The first Progress Report is due 8 months after receipt of this Standard. Interim reports are due semi-annually thereafter.

TABLE A

GENERIC DATA REQUIREMENTS FOR HEPTACHLOR

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1]/
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	B,H,I	Yes	00050054	No	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	B,H,I	No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	TGAI	B,H,I	No		Yes	9 Months
81-7 - Delayed Neurotoxicity - Hen	TGAI	B,H,I	No		No[2]/	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding: Rodent and Nonrodent (Dog)	TGAI	B,H,I	No		No[3]/	
82-2 - 21-Day Dermal - Rabbit	TGAI	B,H,I	No		Reserved[4]/	
82-3 - 90-Day Dermal - Rabbit	TGAI	B,H,I	No		No[5]/	
82-4 - 90-Day Inhalation - Rat	TEP	B,H,I	No		No[6]/	
82-5 - 90-Day Neurotoxicity	TGAI	B,H,I	No		No[2]/	

TABLE A
GENERIC DATA REQUIREMENTS FOR HEPTACHLOR

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1/]
§158.135 Toxicology (continued)						
CHRONIC TESTING:						
83-1 - Chronic Toxicity - Rodent and Non-Rodent	TGAI	B,H,I	Partially	GS0175-001	Yes[7/]	50 Months[10] (8 Months- Progres Report)
83-2 - Oncogenicity - Mouse	TGAI	B,H,I	Yes	GS0173-004	No	
Rat	TGAI	B,H,I	No		Yes[8/]	50 Months[10/] (8 Months- Progres Report)
83-3 - Teratogenicity - Rat and Rabbit	TGAI	B,H,I	No		Yes	15 Months (8 Months- Progres
83-4 - Reproduction - Rat 2-generation	TGAI	B,H,I	Yes	GS0175-001	No	
MUTAGENICITY TESTING:						
84-2 - Gene Mutation	TGAI	B,H,I	Partially	GS0175-003	Yes[9/][13/]	9 Months
84-3 - Structural Chromosomal Aberration	TGAI	B,H,I	Partially	GS0175-003	Yes[10/][13/]	12 Months
84-4 - Other Genotoxic Effects	TGAI	B,H,I	Partially	GS0175-003	Yes[11/][13/]	12 Months 90 Days- Acceptable Protocol)

TABLE A
GENERIC DATA REQUIREMENTS FOR HEPTACHLOR

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[9/]
85-1 - General Metabolism	PAI or PAIRA	H,I	Yes	GS0175-004	No[14/]	
SPECIAL TESTING:						
Optic tissue Pathology		H,I	No		Yes[15/]	To be Determined
Rat Inhalation Study		H,I	No		Yes[6/]	24 Months

[1/] Due dates refer to the number of months following receipt of the Registration Standard by the registrant, unless otherwise indicated.

[2/] Heptachlor is dissimilar to known delayed neurotoxic agents (i.e., organophosphates) and neurotoxicity of the delay type has not been reported in the large number of chemical plant intoxications encountered. Recovery has been complete and relatively rapid when humans were removed from the exposure area. For these reasons, the Agency is not requiring this test.

[3/] The Agency is not requiring 90-day studies, since long-term studies supercede the need for subchronic studies.

[4/] Requirement for submission of a 21-day dermal study is reserved pending the results of the acute dermal toxicity study.

[5/] The Agency recognizes that heptachlor is absorbed dermally and toxicity can ensure from that exposure. However, th target organs have been well delineated from other routes of exposure and therefore, no data are required for this area of study.

[6/] A requirement for a 90 day subchronic inhalation study was originally imposed as part of the Agency's 1984 Data Call-In Notice. The study submitted to the Agency centered on the use of chlordane with only about 10 per cent of the test material being heptachlor. The study is considered invalid for this reason and because the lowest dose tested was not the National Academy of Science (NAS) guideline, as requested in the DCI. A new rat inhalation study must be performed in which the test duration is one year, rather than 90-days, as this exposure period more likely reflects typical human exposure resulting from termiticide use. The lowest dose level must be the NAS guideline level.

[7/] Data gaps exist for chronic feeding testing in rodents (rats) and non-rodents for heptachlor epoxide; and for heptachlor in non-rodents.

§158.135 Toxicology (continued)

8/ A data gap exists for oncogenicity testing in rodents (rats) for heptachlor epoxide.

9/ A mammalian cell gene mutation assay, with established test systems, e.g. mouse lymphoma (L5178Y/TK), or Chinese hamster (CHO/V79/HGPRT) cells *inter alia* , specifically comparing acyivation systems (S9) derived from rat vs. mouse (or hamster) liver microsomes, is required

10/ Somatic cell cytogenetic assays, either *in vitro* or *in vivo* , are required.

11/ The following studies are required:
   a. repair in mammalian cell systems, e.g., primary mouse hepatocytes or established cell lines, by autoradiographic or alkaline elution techniques.
   b. adequately controlled promotion assays, e.g., in cell lines already initiated (by viral transformation), or exposed to known chemical initiators.
   c. mammalian cell transformation in systems with an established data base, e.g., C3H 10 T1/2, BALB 3T3, *inter alia*.
   d. assays for mitotic spindle effects (*in vitro* or *in vivo*), and/or involving other cellular mechanisms (e.g., oncogene activation), *inter alia*.
   e. assays which can distinguish effects on replicative S-phase (scheduled) DNA synthesis from UDS, e.g., in primary hepatocytes from several species (mouse vs. rat/hamster).

12/ The first progress report is due 8 months after receipt of this Standard. Interim reports are due semi-annually thereafter.

13/ This requirement was originally imposed as part of the Agency's 1984 Special Termiticide Data Call-In Notice. Data received in response to that DCI were reviewed in conjunction with the development of this Registration Standard and found to be unacceptable or inconclusive (see footnotes 9,10, and 11).

14/ This requirement was originally imposed as part of the Agency's 1984 Special Termiticide Data Call-In Notice. Acceptable data have been received by the Agency.

15/ Eye tissue from the required two-year rat oncogenicity study must be analyzed by neuropathologists specializing in optic tissue pathology.

TABLE A
GENERIC DATA REQUIREMENTS FOR HEPTACHLOR

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1]/
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING:						
71-1 - Acute Avian Oral Toxicity	TGAI	B,H,I	No		Yes	9 Months
71-2 - Avian Subacute Dietary Upland Game Bird and Waterfowl	TGAI	B,H,I	Yes	00085950	No	
71-3 - Wild Mammal Toxicity	TGAI	N/A				
71-4 - Avian Reproduction Upland Game Bird and Waterfowl	TGAI	B,H,I	No		Reserved[2]/	
71-5 - Simulated Field Testing and Actual Field Testing - Mammals and Birds	TEP	B,H,I	No		Reserved[2]/	
72-1 - Freshwater Fish Toxicity						
- Warmwater and Coldwater Species	TGAI	B,H,I	Yes	GS0144-012	No	
- Unique Formulation (Warmwater Species)	TEP	B,H,I	Yes	00108085 00086221	No	
- Unique Formulation (Coldwater Species)	TEP	B,H,I	Yes	00103882 00086221	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR HEPTACHLOR

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1]
§158.145 Wildlife and Aquatic Organisms (continued)						
AQUATIC ORGANISM TESTING:						
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	B,H,I	Yes	GS0144-012	No	
- Unique Formulation	TEP	B,H,I	Yes	00086221	No	
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI	B,H,I	No		Reserved2/	
72-4 - Fish Early Life Stage, and Aquatic Invertebrate Life Cycle	TGAI	H,I	No		Reserved2/	
72-5 - Fish - Life Cycle	TGAI	H,I	No		Reserved2/	
72-6 - Aquatic Organism Accumulation	TGAI, PAI or Degradation Product	H,I	No		Reserved2/	
72-7 - Simulated Field Testing and Actual Field Testing - Aquatic Organisms	TEP	H,I	No		Reserved2/	

TABLE A
GENERIC DATA REQUIREMENTS FOR HEPTACHLOR

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.145 Wildlife and Aquatic Organisms						
SPECIAL TESTING						
70-1 Aquatic Residue Monitoring		H,I	No		Reserved[2]	

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[1] Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

[2] This requirement is reserved pending the results of the special monitoring study, in which water from sanitary sewer, sumps, and drainage tiles, draining from home foundations treated with heptachlor, is sampled and analyzed for residue of heptachlor.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING HEPTACHLOR

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission1/
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	MP 2/	B,H,I	Partially	00050054	Yes3/	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	MP	B,H,I	No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	MP	B,H,I	No		Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	B,H,I	No		Yes	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	B,H,I	Partially	00066843	Yes3/	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	B,H,I	No		No4/	

1/ Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

2/ Formulation intermediates are also included in the category of manufacturing-use products.

3/ Data are satisfied for a heptachlor technical (74% pure) formulation only.

4/ Due to the extensive human exposure data compiled without reported dermal sensitization, testing is not required.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING HEPTACHLOR

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation 1/	Must Additional Data be Submitted?	Timeframe for Submission2/
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP3/	B,H,I			Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	B,H,I			Yes	6 Months
61-3 - Discussion of Formation of Impurities	MP	B,H,I			Yes	6 Months
Analysis and Certification of Product Ingredients:						
62-1 - Preliminary Analysis	MP	B,H,I			Yes	12 Months
62-2 - Certification of Limits	MP	B,H,I			Yes	12 Months
62-3- Analytical Methods to Verify Certified Limit	MP	B,H,I			Yes	12 Months
Physical And Chemical Characteristics:						
63-2 - Color	MP	B,H,I			Yes	6 Months
63-3 - Physical State	MP	B,H,I			Yes	6 Months
63-4 - Odor	MP	B,H,I			Yes	6 Months

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING HEPTACHLOR

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data? 1/	Bibliographic Citation 1/	Must Additional Data be Submitted?	Timeframe for Submission 2/
§158.120 Product Chemistry (continued)						
Physical and Chemical Characteristics (continued)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	B,H,I			Yes	7 Months
63-12 - pH	MP	B,H,I			Yes	7 Months
63-14 - Oxidizing or Reducing Action	MP	B,H,I			Yes	7 Months
63-15 - Flammability	MP	B,H,I			Yes	7 Months
63-16 - Explodability	MP	B,H,I			Yes	7 Months
63-17 - Storage Stability	MP	B,H,I			Yes	16 Months (8 Months - Progress Report)
63-18 - Viscosity	MP	B,H,I			Yes	7 Months
63-19 - Miscibility	MP	B,H,I			Yes	7 Months
63-20 - Corrosion Characteristics	MP	B,H,I			Yes	7 Months
Other Requirements:						
64-1 - Submittal of Samples	MP	B,H,I			Reserved 4/	

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing-use product. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

§ 158.120 Product Chemistry (continued)

2/ Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

3/ Formulation intermediates are also included in the category of manufacturing-use products.

4/ If samples are needed, the Agency will request them.

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING HEPTACHLOR

Guideline Citation and Name of Test	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data be Submitted?	Timeframe for Submission2/
§158.120 - Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	EP	B,H,I			Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	EP	B,H,I			Yes	6 Months
61-3 - Discussion of Formation of Impurities	EP	B,H,I			Yes	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	EP	B,H,I			Yes	12 Months
62-1 - Certification of Limits	EP	B,H,I			Yes	6 Months
62-3 - Analytical Methods to Verify Certified Limit	EP	B,H,I			Yes	6 Months
Physical and Chemical Characteristics						
63-2 - Color	EP	B,H,I			Yes	6 Months
63-3 - Physical State	EP	B,H,I			Yes	6 Months
63-4 - Odor	EP	B,H,I			Yes	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	EP	B,H,I			Yes	6 Months

TABLE C

PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING HEPTACHLOR

Guideline Citation and Name of Test	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation1/	Must Additional Data be Submitted?	Timeframe for Submission2/
§158.120 - Product Chemistry (continued)						
Physical and Chemical Characteristics (continued)						
63-12 - pH	EP	B,H,I			Yes	6 Months
63-14 - Oxidizing or Reducing Action	EP	B,H,I			Yes	6 Months
63-15 - Flammability	EP	B,H,I			Yes	6 Months
63-16 - Explodability	EP	B,H,I			Yes	6 Months
63-17 - Storage Stability	EP	B,H,I			Yes	12 Months
63-18 - Viscosity	EP	B,H,I			Yes	6 Months
63-19 - Miscibility	EP	B,H,I			Yes	6 Months
63-20 - Corrosion Characteristics	EP	B,H,I			Yes	6 Months
63-21 - Dielectric Breakdown Voltage	EP	H,I			No3/	6 Months
Other Requirements:						
64 - 1 Submittal of Samples	EP,TGAI,PAI	B,H,I			Reserved4/	

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING HEPTACHLOR

§158.120- Product Chemistry (continued)

3/ Not required for termiticide products, since product labeling cautions to avoid use near electrical conduits.
4/ If samples are needed, the Agency will request them.

TABLE C

PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING HEPTACHLOR

Guideline Citation and Name of Test	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission1/
§158.135 Toxicology						
Acute Testing:						
81-1 - Acute Oral Toxicity - Rat	EP	B,H,I	No		Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	EP	B,H,I	No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	EP	B,H,I	No		Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	EP	B,H,I	No		Yes	9 Months
81-5 - Primary Dermal Irritation - Rabbit	EP	B,H,I	No		Yes	9 Months
81-6 - Dermal Sensitzation	EP	B,H,I	No		No2/	
SPECIAL TEST						
Guinea Pig or Rat Inhalation Study	EP	H,I	No		Yes3/	15 Months (90 Days-Acceptable Protocol) (8 Months-Progress Report)

1/ Due dates refer to the number of months following receipt of this Registration Standard by the registrant, unless otherwise indicated.

2/ Due to extensive human exposure data compiled without reported dermal sensitization, testing is not required.

3/ Testing is required to delineate the irritative capabilities to mucous membranes of heptachlor, the solvent, and/or the combination. The study design must include a 7-day exposure period to two groups og guinea pigs, with a 2-week recovery in one group; the second to be sacrificed after 7 days of exposure. Exposures should be for 6-8 hrs/day at levels found in a house on day 1 of termite treatment, and include end-use solvent alone; heptachlor alone, and solvent plus heptachlor. Registrants of products containing the same or similar solvents are encouraged to develop data jointly.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

SUMMARY-2

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

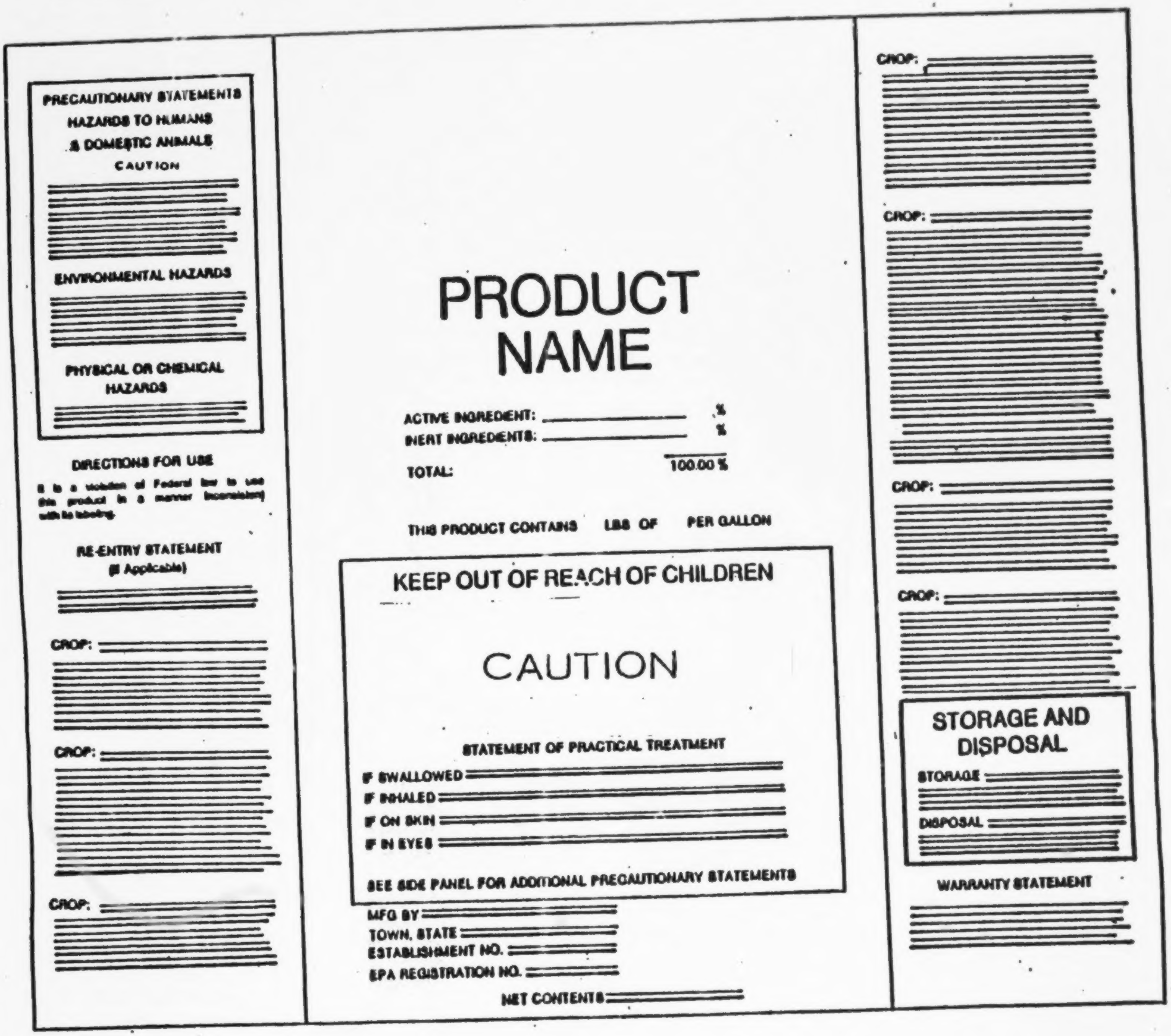
ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL REQUIRED	PLACEMENT ON LABEL PREFERRED	COMMENTS
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

& DOMESTIC ANIMALS

CAUTION

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

CROP: ____

CROP: ____

CROP: ____

PRODUCT NAME

ACTIVE INGREDIENT: ____ %
INERT INGREDIENTS: ____ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED ____
IF INHALED ____
IF ON SKIN ____
IF IN EYES ____

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY ____
TOWN, STATE ____
ESTABLISHMENT NO. ____
EPA REGISTRATION NO. ____

NET CONTENTS ____

CROP: ____

CROP: ____

CROP: ____

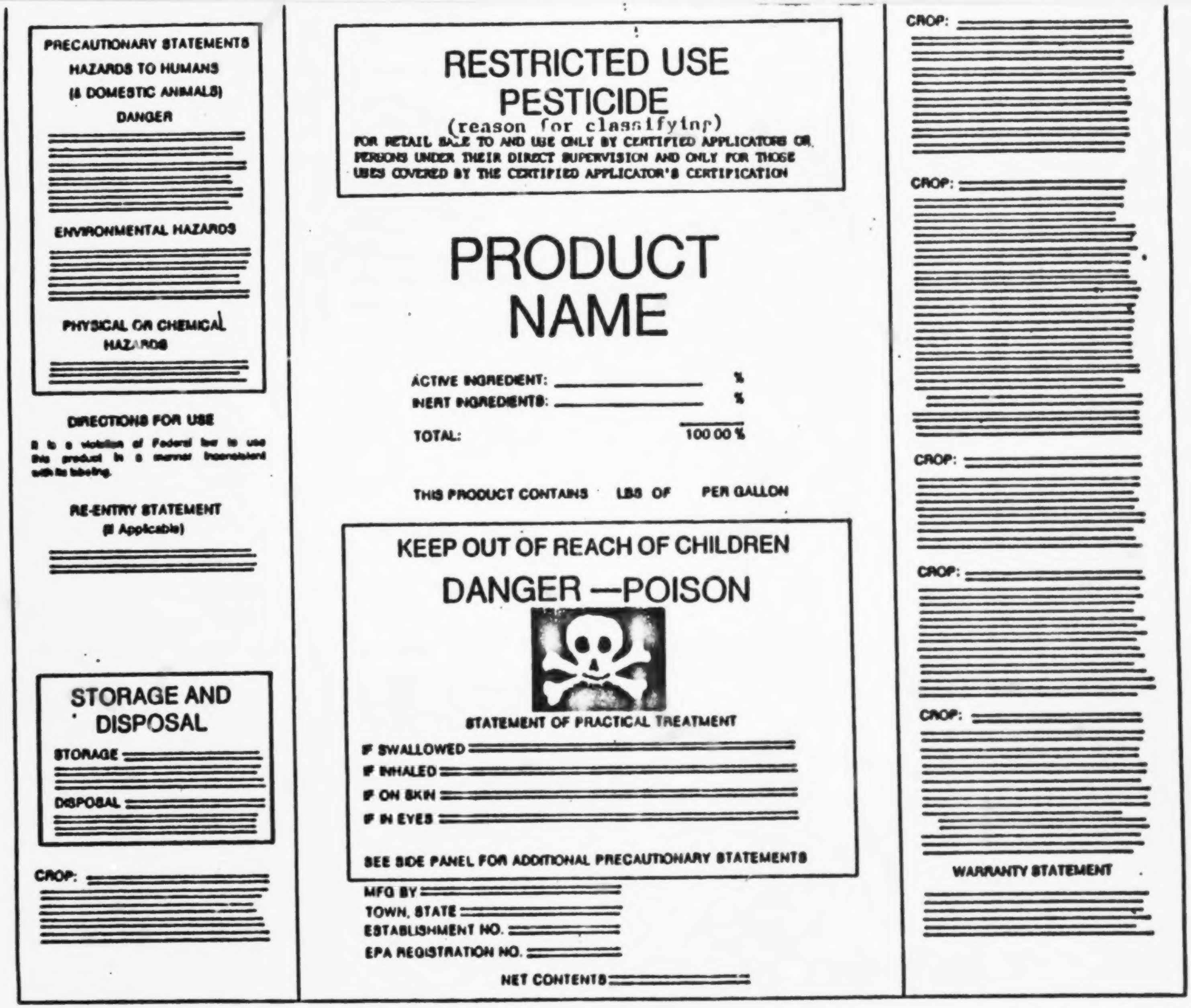
CROP: ____

STORAGE AND DISPOSAL

STORAGE ____

DISPOSAL ____

WARRANTY STATEMENT



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL
HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

STORAGE AND
DISPOSAL

STORAGE

DISPOSAL

CROP:

RESTRICTED USE
PESTICIDE
(reason for classifying)

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

PRODUCT
NAME

ACTIVE INGREDIENT: ____ %
INERT INGREDIENTS: ____ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN
DANGER —POISON

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by

any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) *Name and address of producer, registrant, or person for whom produced.* An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20° C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run par allel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may

appear elsewhere. Specific require
ments concerning content, placement
type size, and prominence are give
below.

(i) *Required front panel statement:*
With the exception of the chil
hazard warning statement, the text r
quired on the front panel of the lab
is determined by the Toxicity Categ
ry of the pesticide. The category is a
signed on the basis of the highe
hazard shown by any of the indicato
in the table below.

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD$_{50}$	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC$_{50}$	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2. thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD$_{50}$	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(*1*) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher

Toxicity Category is not permitte
except when the Agency determine
that such labeling is necessary to pre
vent unreasonable adverse effects o
man or the environment. In no cas
shall more than one human hazar
signal word appear on the front pane
of a label.

(*2*) *Child hazard warning.* Every pe
ticide product label shall bear on th
front panel the statement "keep out o
reach of children." Only in case
where the likelihood of contact wit
children during distribution, market
ing, storage or use is demonstrated b
the applicant to be extremely remote
or if the nature of the pesticide is suc
that it is approved for use on infant
or small children, may the Administra
tor waive this requirement.

(*3*) *Statement of practical treat
ment*—(A) *Toxicity Category I.* A
statement of practical treatment (firs
aid or other) shall appear on the fron
panel of the label of all pesticides fall
ing into Toxicity Category I on th
basis of oral, inhalation or dermal tox
icity. The Agency may, however
permit reasonable variations in th
placement of the statement of practi

cal treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionqry statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of

100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(l) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(3) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely be overlooked under customary cond tions of purchase and use, the stat ment "Restricted Use Pesticide" sha appear.

(B) Directly below this statement the front panel, a summary statemer of the terms of restriction imposed a precondition to registration sha appear. If use is restricted to certifi applicators, the following statement required: "For retail sale to and u only by Certified Applicators or pe sons under their direct supervision a only for those uses covered by the C tified Applicator's certification." however, other regulatory restrictio are imposed, the Administrator w define the appropriate wording for t terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 3232 Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, amended at 43 FR 5786, Feb. 9, 1978]

~~§ 162.11 Criteria for determinations of u reasonable adverse effects.~~

~~(a) *Criteria for Issuance of Noti Intent to Deny Registration, Canc Registration, or to Hold a Hearing* (1) *Presumption.* (i) A rebuttable p sumption shall arise that a notice intent to deny registration pursuant section 3(c)(6) of the Act, a notice intent to cancel registration pursua to section 6(b)(1) of the Act, or notice of intent to hold a hearing determine whether the registratio should be cancelled or denied, as a propriate, shall be issued, upon a d termination by the Administrator th the pesticide meets or exceeds any the criteria for risk set forth in pa graph (a)(3) of this section. Upon su determination, the Administrat shall issue notice by certified mail the applicant or registrant, as the ca may be, stating that the applicant registrant has the opportunity submit evidence in rebuttal of su presumption in accordance with par graph (a)(4) of this section. The appl cant or registrant shall have forty fi (45) days from the date such notice sent to submit evidence in rebuttal the presumption; provided, howe that for good cause shown the Adm istrator may grant an additional six~~

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.
4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes (see list in this Appendix) or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes (see list in this Appendix) or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

   "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

   "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

PESTICIDE ACTIVE INGREDIENTS THAT ARE ACUTE HAZARDOUS WASTES

I. PESTICIDES ON THE "E" LIST (with RCRA # and CAS
[40 CFR 261.33(e)]

Acrolein	P003	107-13-1
Aldicarb	P070	116-06-3
Aldrin	P004	309-00-2
Allyl alcohol	P005	107-18-6
Aluminum phosphide	P006	1302-45-0
4-Aminopyridine (Avitrol)	P008	504-24-5
Arsenic acid	P010	7778-39-4
Arsenic pentoxide	P011	1303-28-2
Arsenic trioxide	P012	1327-53-3
Calcium cyanide	P021	592-01-8
Carbon disulfide	P022	75-15-0
p-Chloroaniline	P024	106-47-8
Cyanides (soluble cyanide salts not otherwise specified)	P030	
Cyanogen chloride	P031	506-77-4
Dieldrin	P037	60-57-1
O,O-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate (disulfoton)	P039	298-04-4
O,O-Diethyl O-pyrazinyl phosphorothioate (Zinophos®)	P040	297-97-2
Dimethoate	P044	60-51-5
O,O-Dimethyl O-p-nitrophenyl phosphorothioate (methyl parathion)	P071	298-00-0
4,6-Dinitro-o-cresol and salts	P047	534-52-1
4,6-Dinitro-o-cyclohexylphenol	P034	131-89-5
Dinoseb	P020	88-85-7
Endosulfan	P050	115-29-7
Endothall	P088	129-67-9
Endrin	P051	72-20-8
Famphur	P097	52-85-7
Fluoroacetamide	P057	640-19-7
Heptachlor	P059	76-48-8
Hexachlorohexahydro-exo,exo-dimethanonaphthalene (Isodrin)	P069	465-73-6
Hydrocyanic acid	P063	74-90-8
Methomyl	P066	16752-77-5
alpha-Naphthylthiourea (ANTU)	P072	86-88-41
Nicotine and salts	P075	54-11-5
Octamethylpyrophosphoramide (OMPA, schradan)	P085	152-16-9
Parathion	P089	56-38-2
Phenylmercuric acetate (PMA)	P092	62-38-4
Phorate	P094	298-02-2
Potassium cyanide	P098	151-50-8
Propargyl alcohol	P102	107-19-7
Sodium azide	P105	26628-22-8
Sodium cyanide	P106	143-33-9
Sodium fluoroacetate	P058	62-74-8

Strychnine and salts	P108	57-24-9 60-41-3
O,O,O,O-Tetraethyl dithiopyrophosphate (sulfotepp)	P109	3689-24-5
Tetraethyl pyrophosphate	P111	107-49-3
Thallium sulfate	P115	7446-18-6
Thiofanox	P045	39196-18-4
Toxaphene	P123	8001-35-2
Warfarin (>0.3%)	P001	81-81-2
Zinc phosphide (>10%)	P122	1314-84-7

50 ACTIVES

II. PESTICIDES DERIVED FROM TRI-, TETRA-, AND PENTACHLOROPHENOLS [40 CFR 261.31]

2-Chloroethyl 2-(2,4,6-trichlorophenoxy) ethyl ether	F027	5324-22-1
Dehydroabietylammonium pentachlorophenoxide	F027	35109-57-0
Erbon	F027	136-25-4
O-ethyl O-(2,4,5-trichlorophenyl) ethylphosphonothioate	F027	327-98-0
2,2'-Methylenebis (3,4,6-trichlorophenol) (Hexachlorophene)	F027	70-30-4
--Potassium salt of	F027	67923-62-0
--Sodium salt of	F027	3247-34-5
--Disodium salt of	F027	5736-15-2
Pentachlorophenol	F027	87-86-5
--Potassium salt of	F027	7778-73-6
--Sodium salt of	F027	131-52-2
--Zinc salt of	F027	2917-32-0
--Zinc salt of N-alkyl $(C_{16}-C_{18})$-1,3-propanediamine	F027	
--Pentachlorophenyl laurate	F027	3772-94-9
Potassium trichlorophenate (2,4,6)	F027	2591-21-1
Potassium trichlorophenate (2,4,5)	F027	35471-43-3
Silvex	F027	93-72-1
--2-Butoxyethyl ester	F027	19398-13-1
--Butoxypolypropoxypropyl ester	F027	53404-07-2
--Butoxypropyl ester	F027	25537-26-2
--Diethanolamine salt	F027	51170-59-3
--Diisopropanolamine salt	F027	53404-09-4
--Dimethylamine salt	F027	55617-85-1
--Dipropylene glycol isobutyl ether ester	F027	53535-26-5
--Ethanolamine salt	F027	7374-47-2
--2-Ethylhexyl ester	F027	53404-76-5
--Isooctyl ester	F027	53404-14-1

--Isopropanolamine salt	F027	53404-13-0
--Monohydroxylaluminum salt	F027	69622-82-8
--Polypropoxypropyl ester	F027	83562-66-7
--Potassium salt	F027	2818-16-8
--Propylene glycol isobutyl ether ester	F027	53466-84-5
--Sodium salt	F027	37913-89-6
--Triethanolamine salt	F027	17369-89-0
--Triethylamine salt	F027	53404-74-3
--Triisopropanolamine salt	F027	53404-75-4
--Tripropylene glycol isobutyl ether ester	F027	53535-30-1
Sodium 2-(2,4,5-trichlorophenoxy) ethyl sulfate	F027	3570-61-4
Tetrachlorophenols	F027	25167-83-3
--Alkylamine*amine salt (as in fatty acids of coconut oil)	F027	
--Potassium salt	F027	53535-27-6
--Sodium salt	F027	25567-55-9
2,4,5-Trichlorophenol	F027	95-95-4
2,4,6-Trichlorophenol	F027	88-06-2
2,4,5-Trichlorophenol salt of 2,6-bis[(dimethylamino)methyl] cyclohexanone	F027	53404-83-4
2,4,5-Trichlorophenol, sodium salt	F027	136-32-3
2,4,6-Trichlorophenol, sodium salt	F027	3784-03-0
2,4,5-Trichlorophenoxyacetic acid	F027	93-79-8
--Alkyl C-12 amine salt	F027	53404-84-5
--Alkyl C-13 amine salt	F027	53404-85-6
--Alkyl C-14 amine salt	F027	53535-37-8
--N,N-diethylethanolamine salt	F027	53404-86-7
--Dimethylamine salt	F027	6369-97-7
--N,N-dimethyllinoleylamine salt	F027	53404-88-9
--N,N-dimethyloleylamine salt	F027	53404-89-0
--N-oleyl-1,3-propylene diamine salt	F027	53404-87-8
--Sodium salt	F027	13560-99-1
--Triethanolamine salt	F027	3813-14-7
--Triethylamine salt	F027	2008-46-0
--Alkyl (C3H7 - C7H9) ester	F027	
--Amyl ester	F027	120-39-8
--Butoxyethoxypropyl ester	F027	1928-58-1
--2-Butoxyethyl ester	F027	2545-59-7
--Butoxypropyl ester	F027	1928-48-9
--Butyl ester	F027	93-79-8
--Dipropylene glycol isobutyl ether ester	F027	53535-31-2
--2-Ethylhexyl ester	F027	1928-47-8
--Isobutyl ester	F027	4938-72-1

--Isopropyl ester	F027	93-78-7
--Propylene glycol isobutyl ether ester	F027	53466-86-7
--Tripropylene glycol isobutyl ether ester	F027	53535-32-3
4-(2,4,5-Trichlorophenoxy)butyric acid [2,4,5-TB]	F027	93-80-1
2-(2,4,5-Trichlorophenoxy)ethyl hydrogen sulfate [2,4,5-TES]	F027	69633-04-1
1,4',5'-Trichloro-2'-(2,4,5-trichlorophenoxy) methanesulfonanilide [Edolan U]	F027	69462-14-2

PESTICIDES THAT ARE TOXIC HAZARDOUS WASTES

PESTICIDES ON THE "F" LIST [40 CFR 261.33(f)] (with	RCRA #, and	CAS #
Acetone	U002	67-64-1
Acrylonitrile*	U009	107-13-1
Amitrole	U011	61-82-5
Benzene*	U019	71-43-2
Bis(2-ethylhexyl)phthalate	U028	117-81-7
Cacodylic acid	U136	75-60-5
Carbon tetrachloride*	U211	56-23-5
Chloral (hydrate) (chloroacetaldehyde)	U034	302-17-0
Chlordane, technical*	U036	57-74-9
Chlorobenzene*	U037	108-90-7
4-Chloro-m-cresol	U039	59-50-7
Chloroform*	U044	67-66-3
o-Chlorophenol	U048	95-57-8
Creosote	U051	8021-39-4
Cresylic acid (cresols)*	U052	1319-77-3
Cyclohexane	U056	110-82-7
Cyclohexanone	U057	108-94-1
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one (Kepone, chlordecone)	U142	143-50-0
1,2-Dibromo-3-chloropropane (DBCP)	U066	96-12-8
Dibutyl phthalate	U069	84-74-2
S-2,3-(Dichloroallyl diisopropylthiocarbamate) (diallate,Avadex)	U062	2303-16-4
o-Dichlorobenzene*	U070	95-50-1
p-Dichlorobenzene*	U072	106-46-7
Dichlorodifluoromethane (Freon 12®)	U075	75-71-8
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide, Kerb®)	U192	23950-58-5
Dichloro diphenyl dichloroethane (DDD)	U060	72-54-8
Dichloro diphenyl trichloroethane (DDT)	U061	50-29-3
Dichloroethyl ether	U025	1191-17-9
2,4-Dichlorophenoxyacetic, salts and esters (2,4-D)*	U240	94-75-7
1,2-Dichloropropane	U083	8003-19-8
1,3-Dichloropropene (Telone)	U084	542-75-6
Dimethyl phthalate	U102	131-11-3
Epichlorohydrin (1-chloro-2,3-epoxypropane)	U041	106-89-8
Ethyl acetate	U112	141-78-6
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)	U038	510-15-6

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*Proposed for deletion by TCLP proposal

Ethylene dibromide (EDB)	U067	106-93-4
Ethylene dichloride*	U077	107-06-2
Ethylene oxide	U115	75-21-8
Formaldehyde	U122	50-00-0
Furfural	U125	98-01-1
Hexachlorobenzene*	U127	118-74-1
Hexachlorocyclopentadiene	U130	77-47-4
Hexachloroethane*	U131	67-72-1
Hydrofluoric acid	U134	7664-39-3
Isobutyl alcohol*	U140	78-83-1
Lead acetate	U144	301-04-2
Lindane*	U129	58-89-9
Maleic hydrazide	U148	123-33-1
Mercury	U151	7439-97-6
Methoxychlor*	U247	72-43-5
Methyl alcohol (methanol)	U154	67-56-1
Methyl bromide	U029	74-83-9
Methyl chloride	U045	74-87-3
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene) [acute waste per 261.31]	U132	70-30-4
Methylene chloride*	U080	75-09-2
Methyl ethyl ketone*	U159	78-93-3
4-Methyl-2-pentanone (methyl isobutyl ketone)	U161	108-10-1
Naphthalene	U165	91-20-3
Nitrobenzene*	U169	98-95-3
p-Nitrophenol	U170	100-02-7
Pentachloroethane	U184	76-01-7
Pentachloronitrobenzene (PCNB)	U185	82-68-8
Pentachlorophenol* [acute waste per 261.31]	U242	87-86-5
Phenol*	U188	108-95-2
Pyridine*	U196	110-86-1
Resorcinol	U201	108-46-3
Safrole	U203	94-59-7
Selenium disulfide	U205	7488-56-4
Silvex [acute waste per 261.31]	U233	93-72-1
1,1,2,2-Tetrachloroethane*	U209	79-34-5
Tetrachloroethylene*	U210	127-18-4
2,3,4,6-Tetrachlorophenol* [acute waste per 261.31]	U212	
Thiram	U244	137-26-8
Toluene*	U220	108-88-3
1,1,1-Trichloroethane* (methyl chloroform)	U226	71-55-6
Trichloroethylene*	U228	79-01-6
Trichloromonofluoromethane (Freon 11®)	U121	75-69-4
2,4,5-Trichlorophenol* [acute waste per 261.31]	U230	95-95-4
2,4,6-Trichlorophenol* [acute waste per 261.31]	U231	88-06-2

2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)* [acute waste per 261.31]	U232	93-76-5
Warfarin (<0.3%)	U248	81-81-2
Xylene	U239	1330-20-7
Zinc phosphide (<10%)	U249	1314-84-7

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III. USE INDEX APPENDIX

EPA Compendium of Acceptable Uses

HEPTACHLOR

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HEPTACHLOR*
(AND RELATED COMPOUNDS)**

TYPE PESTICIDE: Insecticide

FORMULATIONS:
Tech (72%)
FI (3.7%, 25.6%, 26.9%)
G (5%)
EC (0.25 lb/gal, 1 lb/gal, 1.5 lb/gal, 2 lb/gal, 2.01 lb/gal, 2.1 lb/gal, 2.2 lb/gal, 2.5 lb/gal, 3 lb/gal, 8.51%)

GENERAL WARNINGS AND LIMITATIONS: RESTRICTED USE PESTICIDE. Heptachlor is toxic to fish and wildlife. Keep out of lakes, streams or ponds. Applicators must wear water resistant hat, lightweight protective suit or coveralls, unlined chemical-resistant gloves (natural rubber, neoprene, or polyethylene), and unlined lightweight boots. MSHA/OSHA approved respirators are required for applications in enclosed areas such as crawl spaces. Mixer/loaders must wear goggles or a face shield, chemical-resistant apron, long-sleeved shirt, long pants, or coveralls, and unlined, mid-forearm to elbow length chemical-resistant gloves when mixing, loading, or otherwise handling the concentrate.
Do not apply chlordane in or around poultry houses, barns, silos, milk houses, or other structures or enclosures where livestock or poultry is held, or where food/feed is stored, prepared or processed. Do not apply chlordane to plenum houses (houses where the crawlspace beneath the building is used to circulate heated or cooled air without ductwork). Do not contaminate feed and foodstuffs.

Agricultural Crop Tolerances:

Alfalfa	0.0 ppm
Apples	0.0 ppm
Barley	0.0 ppm
Beans, Lima	0.0 ppm
Beans, Snap	0.1 ppm
Beets	0.0 ppm
Beets, Sugar	0.0 ppm
Brussels Sprouts	0.0 ppm
Cabbage	0.1 ppm
Carrots	0.0 ppm
Cauliflower	0.0 ppm
Cherries	0.0 ppm
Clover	0.0 ppm
Clover, Sweet	0.0 ppm
Corn	0.0 ppm
Cotton, Seed	0.0 ppm
Cowpeas	0.0 ppm
Grapes	0.0 ppm
Grasses, Pasture	0.0 ppm
Grasses, Range	0.0 ppm
Kohlrabi	0.0 ppm
Lettuce	0.1 ppm
Meat	0.0 ppm

*heptachlorotetrahydro-4,7-methanoindene
**Percentages of related compounds not reflected in this entry.

GENERAL WARNINGS AND LIMITATIONS (continued)

Milk	0.0 ppm
Oats	0.0 ppm
Onions	0.0 ppm
Peaches	0.0 ppm
Peanuts	0.0 ppm
Peas	0.0 ppm
Peas, Black-eyed	0.0 ppm
Pineapples	0.0 ppm
Potatoes	0.0 ppm
Radishes	0.0 ppm
Rutabagas	0.1 ppm
Rye	0.0 ppm
Sorghum, Grain (Milo)	0.0 ppm
Sugarcane	0.0 ppm
Sweet Potatoes	0.0 ppm
Tomatoes	0.0 ppm
Turnips (with tops)	0.0 ppm
Wheat	0.0 ppm

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	TERRESTRIAL NON-FOOD CROP		
	(Noncrop, Wide Area, and General Indoor/Outdoor Treatments)		
680000A	Buried Cable Closures		
SASAYA	Fire ant	0.2 oz/buried cable closure size 1 sq.ft (5% G)	Application in buried pod mounted electric power transformers and cable television and telephone pedestals. Open plastic bag and pour entire contents directly into buried cable closure. One bag will treat buried closures size 1 square foot.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	DOMESTIC OUTDOOR		
	(Wood or Wood Structure Protection Treatments)		
64000NA	Terrestrial Structures		
MGDAGA	Subterranean termites (including Coptotermes, Heterotermes, Reticulitermes, and Zootermopsis spp.)	0.5-1% emulsion (1.5, 2, 2.01, 2.2, 2.5, 3 lb/gal EC) —OR MAI— 0.06% emulsion (0.25 lb/gal EC) or 0.2-0.5% emulsion (1, 2, 2.1 lb/gal EC) (8.51% EC)	Soil contact wood protection treatment. Use limited to professional pest control operators. These formulations are designed for treatment of soil to establish a barrier which is lethal to termites. Heptachlor must be adequately dispersed in the soil to provide a barrier between the wood in the structure and the termite colonies in the soil or to control termites living in the structure. It is necessary for the effective use of heptachlor that the service technician be familiar with current control practices including trenching, rodding, subslab injection, and low pressure spray application. These techniques must be correctly employed to prevent or control infestations by subterranean termite species of Coptotermes, Heterotermes, Reticulitermes and Zootermopsis. Choice of appropriate procedures includes consideration of such variable factors as the design of the structure, water table, soil type, soil compaction, grade conditions and location and type of domestic water supplies. The biology and behavior of the involved termite species are important factors to be known as well as suspected location of the colony and severity of the infestation within the structure to be protected. For advice concerning current control practices for specific local conditions, consult resources in structural pest control. Annual inspections of the treated area should be made. Soil should not be treated when excessively wet. The termites' source of moisture

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations

Terrestrial Structures (continued)

should be eliminated by providing a chemical barrier and/or repairing faulty construction.

Contamination of public and private water supplies must be avoided by following these precautions: Use antiback-flow equipment or procedures to prevent syphonage of pesticide back into water supplies.

Do not treat soil that is water saturated or frozen. Consult state and local specifications for recommended distances of treatment areas from wells, and refer to Federal Housing Administration (F.H.A.) Specifications for further guidance.

All nonessential wood and cellulose containing materials, including scrap wood and form boards, should be removed from around foundation walls, crawl spaces, and porches.

PRECONSTRUCTION SUBTERRANEAN TERMITE TREATMENT

Effective preconstruction subterranean termite control requires the establishment of an unbroken vertical and/or horizontal chemical barrier between wood in the structure and the termite colonies in the soil. To meet F.H.A. termite proofing requirements, follow the latest edition of the Housing and Urban Development (H.U.D.) Minimum Property Standards. After grading is completed and prior to the pouring of the slab, slab supported/constructed porches, or entrance platforms, make the following treatments. Applications shall be made by a low pressure spray for horizontal barriers over areas intended for covering floors, porches, and other critical areas. Establish a vertical barrier in areas such as around the base of foundations, plumbing, back-filled soil against foundation walls, and other critical areas.

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations

Terrestrial Structures (continued)

1. Where it is necessary to produce a horizontal barrier, apply the emulsion at the rate of 1 gallon of emulsion per 10 square feet to dirt fill. If fill is washed gravel or other coarse material, apply at 1.5 gallons of emulsion per 10 square feet. It is important that the emulsion reaches the soil substrate.
    a. If concrete slabs cannot be poured over soil the same day it has been treated, a waterproof cover, such as polyethylene sheeting, should be placed over the soil. This is not necessary if foundation walls have been installed around the treated soil.
2. To produce a vertical barrier, apply the emulsion at the rate of 4 gallons of emulsion per 10 linear feet per foot of depth.
    a. Rodding and/or trenching applications should not be made below the top of the footing.
    b. Trench need not be wider than 6 inches.
    c. Rod holes should extend from the base of the trench to the top of the footing, and should be spaced (about 1 foot) to provide a continuous barrier.
    d. Emulsion should be mixed with the soil as it is being replaced in the trench. Cover treated soil with a layer of untreated soil.
3. Hollow block foundations or voids of masonry should be treated to make a continuous chemical barrier in voids. Apply at the rate of 2 gallons of emulsion per 10 linear feet so it will reach the footing.

Site and Pest | Dosages and Formulation(s) | Tolerance, Use, Limitations

Terrestrial Structures (continued)

4. For crawl spaces apply at the rate of 4 gallons of emulsion per 10 linear feet per foot of depth from grade to bottom of foundations. Application may be made by rodding, low pressure spray, and/or trenching. Treat both sides of foundation and around all piers and pipes.
    a. Rod holes should be spaced (about 1 foot) to provide a continuous chemical barrier.
    b. Trench need not be wider than 6 inches nor below the foundation. The emulsion should be mixed with the soil as it is being replaced in the trench. Cover the treated soil with a layer of untreated soil.
    c. Do not apply in any manner to an area intended as a plenum air space.
    d. Do not apply as an overall treatment to soil in crawl spaces.

All holes drilled in construction elements for treatment should be securely plugged.

POSTCONSTRUCTION TREATMENTS

Postconstruction applications shall be made by injection, rodding, low pressure spray, and/or trenching. Do not apply emulsion until location of heat or air conditioning ducts, vents, water and sewer lines, or electrical conduits are known and identified. Extreme caution must be taken to avoid contamination of these structural elements and airways. Do not apply in any manner to an area intended as a plenum air space.

1. For slab-on-ground construction apply at the rate of 4 gallons of emulsion per 10 linear feet. Application may be made by sub-

Terrestrial Structures (continued)

slab injection. Injectors should not extend beyond the tops of the footings. Treat along the outside of the foundation and where necessary on the inside of foundation walls. Treatment may also be required along 1 side of interior partitions and along all cracks and expansion joints.

  a. Drill holes in the slab to provide a continuous chemical barrier.
  b. Where necessary, drill through the foundation walls from the outside and force the emulsion just beneath the slab or along all the cracks and expansion joints and other critical areas.
  c. For shallow foundations, 1 foot or less, dig a narrow trench approximately 6 inches wide along the outside of the foundation walls. Do not dig below the bottom of the foundation. The emulsion should be applied to the trench and the soil at the rate of 4 gallons of emulsion per 10 linear feet as the soil is replaced in the trench. Cover the treated soil with a layer of untreated soil.
  d. For foundations deeper than 1 foot follow rates for basements.

2. Hollow block foundations or voids of masonry should be treated to make a continuous chemical barrier in voids. Apply at the rate of 2 gallons of emulsion per 10 linear feet.
3. For basements apply at the rate of 4 gallons of emulsion per 10 linear feet. Where footings are greater than 1 foot of depth

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations

Terrestrial Structures (continued)

from the grade to the bottom of the foundation, application may be made by trenching and/or rodding. Treat outside of foundation walls, and if necessary along inside of foundation walls, along cracks in basement floors, along interior load bearing walls, around sewer pipes, conduits, and piers.

4. In crawl spaces apply at the rate of 4 gallons of emulsion per 10 linear feet per foot of depth from grade to bottom of foundation. Application may be made by rodding, and/or trenching. Treat both sides of foundation and around all piers and pipes.
    a. Rod holes should be spaced (about 1 foot) to provide a continuous chemical barrier.
    b. Trench need not be wider than 6 inches nor below the foundations. The emulsion should be mixed with the soil as it is replaced in the trench. Cover the treated soil with a layer of untreated soil.
    c. Do not apply in any manner to an area intended as a plenum air space. After treatment, securely plug all holes drilled in construction elements.
    d. Do not apply as an overall treatment to soil in crawl spaces.

All holes drilled in construction elements for treatment should be securely plugged.

RETREATMENT RESTRICTIONS

Retreatment for subterranean termites should only be made when there is evidence of reinfestations subsequent to the initial treatment, or

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations

Terrestrial Structures (continued)

there has been a disruption of the chemical barrier in the soil due to construction, excavations, or landscaping. Reapplication should be made as a spot treatment to these areas. Avoid annual retreatment of the entire premises.

OR MAI

May be formulated with chlordane, technical.

INDOOR

(Wood or Wood Structure Protection Treatments)

64000NA Terrestrial Structures

Refer to DOMESTIC OUTDOOR, (Wood or Wood Structure Protection Treatments), Terrestrial Structures.

IV. BIBLIOGRAPHY APPENDICES

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

  (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

  (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

  (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

  (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Heptachlor Standard

MRID	CITATION
00050054	Goldenthal, E.I.; Wazeter, F.X.; Dean, W.P. (1974) Acute Toxicity Studies in Rats and Rabbits: IRDC Report No. 163-294. (Unpublished study received January 7, 1977 under 876-7; prepared by International Research and Developmemnt Corp. Chicago, Ill.; CDL:227550-A)
00066843	Goldenthal, E.I.; Wazeter, F.X.; Dean, W.P. (1972) Primary Skin Irritation and Corrosive Hazard Study in Albino Rabbits: IRDC Report No. 163-173. (Unpublished study received Jan 7, 1977 under 876-7; prepared by International Research and Development Corp., submitted by Velsicol Chemical Corp., Chicago, Ill.; CDL:227545-A)
00085950	Heath, R.G.; Spann, J.W.; Hill, E.F.; et al. (1972) Comparative Dietary Toxicities of Pesticides to Birds. By U.S. Fish and Wildlife Service, Patuxent Wildlife Research Center. ?: USFWS. (Special scientific report—wildlife no. 152; pp. 23,27, 30,33-36,38-41,44 only; published study; CDL:070329-E)
00086221	Union Carbide Corporation (1976) Acute Toxicity of Chlorohepton #6 to Bluegill Sunfish, Lepomis macrochirus Rafinesque, Rainbow Trout, Salmo gairdneri Richardson, and the Water Flea, Daphnia magna Staus. (Unpublished study received Dec 22, 1976 under 876-181; submitted by Velsicol Chemical Corp., Chicago, Ill.; CDL:227407-I)
00103882	Bentley, R. (1974) Acute Toxicity of Gold Crest Termide to Rainbow Trout (Salmo gairdneri). (Unpublished study received Jan 29, 1975 under unknown admin. no.; prepared by Bionomics, EG & G Environmental Consultants, submitted by Velsicol Chemical Corp., Chicago, IL; CDL:235576-A)
00108085	Bentley, R. (1974) Acute Toxicity of Gold Crest Termide to Bluegill (Lepomis macrochirus). (Unpublished study received Jan 29, 1975 under unknown admin. no.; prepared by Bionomics, EG & G Environmental Consultants, submitted by Velsicol Chemical Corp., Chicago, IL; CDL:131013-A)
GS0175-001	U.S. EPA (1972) Pesticidal Aspects of Heptachlor in Relation to Man and the Environment. Unpublished report prepared by Special Pesticide Review Group. 79 p.
GS0175-003	Mauer, I. (1986) The Mutagenicity Assessment (Gene-Tox Profile) of Heptachlor/Heptachlor Epoxide: Addendum to the Registration Standard. Memorandum to Henry Spencer dated November 25, 1986. 27 p.

OFFICE OF PESTICIDE PROGRAMS

REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Heptachlor Standard

MRID	CITATION
GS0173-003	Felkner, I. (1986) Overview: Heptachlor Metabolism in Mammals. EPA Contract No. ________. Dynamac Corp., No. ____. Unpublished review ________________.
GS0173-004	U.S. EPA (1985) Carcinogenicity Risk Assessment for Chlordane and Heptachlor/Heptachlor Epoxide. Unpublished report prepared by Carcinogen Assessment Group. 138 p.
GS0144-012	Johnson, W.; Finley, M. (1980) Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates. USDI Publication 137, Washington, D.C.

V. FORMS APPENDICES

OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

Attach separate page with a list of the data requirements your company agrees to satisfy.

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

Attach list of data requirements

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.____________________ Date ____________________

Guidance Document for ______________________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

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FORMULATOR'S EXEMPTION STATEMENT
(40 CFR 152.85)

EPA File Symbol/Reg. No. ______________ Product Name ______________________

Applicant's Name and Address ____

____

____

____

As an authorized representative of the applicant for registration of the product identified above, I hereby certify that:

(1) This product contains the active ingredient(s): __________________

____

____

(2) Each active ingredient listed in paragraph (1) is present solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) Indicate by circling (A) or (B) below which paragraph applies:

(A) An accurate Confidential Statement of Formula (EPA Form 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

(B) The Confidential Statement of Formula dated __________ on file with the EPA is complete, current and accurate and contains the information required on the current CSF Form No. 8570-4. The registered source(s) of the active ingredient(s) listed in paragraph (1) is/are listed below:

Active ingredient	Source: Product name and Reg. No.

Signature ______________________________

Date ______________ Title ______________________________

EPA Form (April 1985)